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(54) Title: METHODS AND APPARATUS FOR SECURING AND DEPLOYING TISSUE ANCHORS

(57) Abstract: Methods and apparatus for securing and deploying tissue anchors are described herein. A tissue manipulation assembly is pivotably coupled to the distal end of a tubular member. A reconfigurable launch tube is also pivotably coupled to the tissue manipulation assembly, which may be advanced through a shape-lockable endoscopic device, a conventional endoscope, or directly by itself into a patient. A second tool can be used in combination with the tissue manipulation assembly to engage tissue and manipulate the tissue in conjunction with the tissue manipulation assembly. A deployment assembly is provided for securing engaged tissue via one or more tissue anchors, the deployment assembly also being configured to disengage the anchors endoluminally or laparoscopically by applying thermal energy through at least one suture cutting element disposed along the deployment assembly.

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METHODS AND APPARATUS FOR SECURING AND DEPLOYING TISSUE ANCHORS

FIELD OF THE INVENTION

[0001] The present invention relates to methods and apparatus for securing and deploying tissue anchors. More particularly, the present invention relates to methods and apparatus for endoluminally or laparoscopically securing and deploying anchors within or against tissue, for instance, to form and/or secure tissue folds or to approximate regions of tissue, etc.

BACKGROUND OF THE INVENTION

[0002] A number of surgical techniques have been developed to treat various gastrointestinal disorders. One such example of a pervasive disorder is morbid obesity. Conventional surgical treatment for morbid obesity typically includes, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0003] Furthermore, the sutures or staples that are often used in surgical procedures for gastrointestinal disorders typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen, for instance, includes four tissue layers, where the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer, and where the serosa layer is the outer-most tissue layer.

[0004] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should

ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intra-operatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

[0005] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0006] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0007] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally.

[0008] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

SUMMARY OF THE INVENTION

[0009] An example of a tool which may be utilized for endoluminally accessing tissue may generally comprise a flexible catheter or tubular body which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. The tubular body may be configured to be torqueable such that when a control handle is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along the flexible body such that the distal end of body is advanced, withdrawn, or rotated in a corresponding manner.

[0010] A tissue manipulation assembly may be located at the distal end of the tubular body and is generally used to contact and form tissue folds, as mentioned above. The tissue manipulation assembly may be connected to the distal end of the tubular body via a pivotable coupling, and a lower jaw member may extend distally from the pivotable coupling with an upper jaw member, in this example, pivotably coupled to the lower jaw member via a jaw pivot. The location of the jaw pivot may be positioned at various locations along the lower jaw depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., on the surface or surfaces of the jaw members to facilitate the adherence of tissue therebetween.

[0011] A launch tube may extend from the handle, through tubular body, and distally from the end of tubular body where a distal end of the launch tube is pivotally connected to the upper jaw member at a pivot. A distal portion of the launch tube may be pivoted into position within a channel or groove defined in upper jaw member to facilitate a low-profile configuration of the tissue manipulation assembly. When articulated, either via the launch tube or other mechanism, the jaw members may be urged into an open configuration to receive tissue in the jaw opening between the jaw members.

[0012] In operation, a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus. Such an endoscopic assembly may generally comprise an endoscopic device, which may have a distal portion that may be articulated and steered to position its distal end anywhere within the stomach. Once desirably configured, the assembly may then be locked or

rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered therethrough.

[0013] The tissue manipulation assembly may be delivered into the patient while in a low-profile configuration, e.g., transorally, through the shape-lockable endoscopic assembly, through an endoscope, an endoscopic device, or directly. Once desirably positioned, the launch tube may be urged proximally via its proximal end at handle. Because the jaw assembly pivot and the relative positioning of the upper jaw pivot along lower jaw member and launch tube pivot along upper jaw member, the proximal movement of the launch tube may effectively articulate upper jaw into an expanded jaw configuration. Proximally urging the launch tube may also urge the lower jaw member to pivot about the assembly pivot and form an angle relative to a longitudinal axis of the tubular body. The opening of the upper jaw relative to the lower jaw creates a jaw opening for grasping or receiving tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to the jaw assembly pivot or within the pivot itself.

[0014] A second tool for initially engaging the tissue region of interest may also be deployed and utilized to engage the tissue and to position the engaged tissue between the jaws of the jaw assembly. Any number of tools may be used in combination with the tissue manipulation assembly. Once the tissue has been engaged between the jaw members, a needle assembly may be urged through the launch tube to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue.

[0015] Once the one or more tissue anchors having been deployed, the tissue may be secured via an anchor deployment assembly, which may generally comprise an elongate member adapted for advancement within a body lumen of the patient and being further adapted to deploy at least one tissue anchor having a length of suture depending therefrom, wherein the elongate member comprises a suture cutting element disposed thereon which is adapted to sever a portion of the suture via thermal energy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Fig. 1A shows a side view of one variation of a tissue manipulation assembly having a flexible body and a handle.

[0017] Fig. 1B illustrates a detail side view of a tissue manipulation assembly in a low-profile configuration connected to the distal end of the tubular body via a pivotable coupling.

[0018] Figs. 2A to 2C illustrate a method for articulating the tissue manipulation assembly from a low-profile configuration to an opened configuration and to a closed jaw configuration for clamping upon tissue, respectively.

[0019] Figs. 3A and 3B show detail perspective views of the tissue manipulation assembly in an open and clamped configuration, respectively.

[0020] Fig. 4 shows an assembly view of how a needle deployment assembly may be introduced through a handle and tubular body of the tissue manipulation assembly.

[0021] Fig. 5A shows a detailed assembly view of the needle deployment assembly from Fig. 4.

[0022] Fig. 5B shows an exploded assembly view of the needle deployment assembly from Fig. 5A.

[0023] Fig. 6 illustrates one example in which a shape-lockable endoscopic assembly may be advanced into a patient's stomach per-orally and through the esophagus with a tissue manipulation assembly advanced through a first lumen and a tissue engagement member advanced through a second lumen.

[0024] Fig. 7 illustrates a tissue manipulation assembly and examples of various tools which may be used in combination with the tissue manipulation assembly.

[0025] Figs. 8A to 8D illustrate an example for performing an endoluminal tissue manipulation and securement procedure utilizing a tissue manipulation assembly in combination with a separate tissue grasping tool within, e.g., a patient's stomach.

[0026] Fig. 9A shows one variation where a single tissue fold may be secured between tissue anchors using the tissue manipulation assembly.

[0027] Fig. 9B shows another variation where two or more tissue folds may be secured between tissue anchors using the tissue manipulation assembly.

[0028] Figs. 10A and 10B illustrate a variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a number of reinforcement members or bars may be positioned along the launch tube to increase its column strength.

[0029] Figs. 11A and 11B illustrate another variation of the tissue manipulation assembly in a perspective and cross-sectional view, respectively, where a pull wire may be routed through the launch tube to facilitate articulation of the launch tube and/or jaw assembly.

[0030] Fig. 12 illustrates yet another variation of the tissue manipulation assembly which may also utilize a pull wire connected directly to the launch tube.

[0031] Fig. 13 illustrates an exploded view of a variation of an anchor assembly and needle deployment assembly.

[0032] Fig. 14 illustrates an assembly view, partially in section, of the anchor assembly and needle deployment assembly variation of Fig. 13.

[0033] Figs. 15A to 15F illustrate an exemplary method of using the anchor assembly and needle deployment assembly variation of Figs. 13 and 14.

[0034] Fig. 16 illustrates a variation of the suture element for use with the anchor assembly and needle deployment assembly of Figs. 13 to 15.

[0035] Fig. 17 illustrates a variation of the needle for use with the anchor assembly and needle deployment assembly variation of Figs. 13 to 15.

[0036] Fig. 18 illustrates a variation of the control mechanisms for use with the needle deployment assemblies of Figs. 13 to 17.

[0037] Figs. 19A to 19C illustrate an exemplary method of using another variation of the anchor assembly and needle deployment assembly.

[0038] Figs. 20A to 20C are schematic views illustrating another variation of the needle deployment assembly.

[0039] Figs. 21A to 21C illustrate another variation of the needle deployment assembly utilizing a release suture or wire which may be routed through a looped terminal end of a suture element.

[0040] Figs. 22A to 22C illustrate yet another variation of the needle deployment assembly utilizing a reconfigurable hook element which may configure itself from a hooked configuration to an open or straightened configuration.

[0041] Figs. 23A to 23C illustrate yet another variation of the needle deployment assembly utilizing a release suture or wire with an obstructive element to be released from the release suture or wire.

[0042] Figs. 24A to 24C illustrate yet another variation of the needle deployment assembly utilizing a suture cutting thermal element for releasing the suture and anchor assembly.

[0043] Figs. 25A and 25B show partial cross-sectional side and assembly views, respectively, of the suture cutting thermal element assembly of Figs. 24A to 24C.

[0044] Figs. 26A and 26B show side and partial cross-sectional views, respectively, of another suture cutting thermal element.

[0045] Figs. 27A and 27B show partial cross-sectional side and end views of yet another suture cutting thermal element.

[0046] Fig. 28 shows an example of a cyclical timing profile for heating the thermal element.

[0047] Fig. 29A shows another pusher variation having a circumferential cutting edge disposed at the distal end of the pusher.

[0048] Fig. 29B shows the instrument of Fig. 29A abutted against a locking mechanism for cinching of the tissue anchors against a tissue surface.

[0049] Figs. 30A to 30C illustrate an alternative method for severing the suture utilizing the tissue manipulation assembly.

[0050] Figs. 31A to 31B illustrate examples for incorporating a cutting blade or element along regions of the tissue manipulation assembly.

[0051] Fig. 32 illustrates another variation of a needle deployment assembly which may endoluminally deploy tissue anchors as well as cinch and release anchor assemblies.

[0052] Fig. 33A illustrates the variation of Fig. 32 having deployed a distal anchor into plicated tissue.

[0053] Figs. 33B and 33C show partial cross-sectional views of the control or housing and the distal portion of the sheath of Fig. 33A illustrating advancement of the tissue anchors, respectively.

[0054] Fig. 34A illustrates the variation of Fig. 32 having deployed both tissue anchors into the plicated tissue prior to cinching of the anchors.

[0055] Figs. 34B and 34C show partial cross-sectional views of the control or housing and the distal portion of the sheath of Fig. 34A illustrating advancement of both tissue anchors, respectively.

[0056] Fig. 35A illustrates the variation of Fig. 32 where the tissue anchors are cinched towards one another for securing the tissue.

[0057] Figs. 35B and 35C show partial cross-sectional views of the control or housing and the distal portion of the sheath of Fig. 35A illustrating cinching of the tissue anchors, respectively.

[0058] Fig. 36A illustrates the variation of Fig. 32 where the cinched tissue anchors are released from the needle deployment assembly.

[0059] Figs. 36B and 36C show partial cross-sectional views of the control or housing and the distal portion of the sheath of Fig. 36A illustrating release of the cinched tissue anchors, respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0060] In manipulating tissue or creating tissue folds, a having a distal end effector may be advanced endoluminally, e.g., transorally, transgastrically, etc., into the patient's body, e.g., the stomach. The tissue may be engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body. Examples of creating and forming tissue plications may be seen in further detail in U.S. Pat. App. Serial No. 10/955,245 filed September 29, 2004, which has been incorporated herein by reference above, as well as U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

[0061] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned via an endoscopic apparatus for contacting a tissue wall of the gastrointestinal lumen, creating one or more tissue folds, and deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0062] An illustrative side view of one example of a tool which may be utilized for endoluminally accessing tissue is shown in Fig. 1A, which shows assembly **10**. The assembly **10** generally comprises a flexible catheter or tubular body **12** which may be configured to be sufficiently flexible for advancement into a body

lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body **12** may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when handle **16** is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along body **12** such that the distal end of body **12** is advanced, withdrawn, or rotated in a corresponding manner.

[0063] Tissue manipulation assembly **14** is located at the distal end of tubular body **12** and is generally used to contact and form tissue folds, as mentioned above. Fig. 1B shows an illustrative detail side view in which tissue manipulation assembly **14** may be seen connected to the distal end of tubular body **12** via a pivotable coupling **18**. Lower jaw member **20** extends distally from the pivotable coupling **18** and upper jaw member **22**, in this example, may be pivotably coupled to lower jaw member **20** via jaw pivot **26**. The location of jaw pivot **26** may be positioned at various locations along lower jaw **20** depending upon a number of factors, e.g., the desired size of the "bite" or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. One or both jaw members **20, 22** may also have a number of protrusions, projections, grasping teeth, textured surfaces, etc., **24** on the surface or surfaces of the jaw members **20, 22** facing one another to facilitate the adherence of tissue between the jaw members **20, 22**.

[0064] Launch tube **28** may extend from handle **16**, through tubular body **12**, and distally from the end of tubular body **12** where a distal end of launch tube **28** is pivotally connected to upper jaw member **22** at launch tube pivot **30**. A distal portion of launch tube **28** may be pivoted into position within a channel or groove defined in upper jaw member **22**, to facilitate a low-profile configuration of tissue manipulation assembly **14**. When articulated, either via launch tube **28** or other mechanism, as described further below, jaw members **20, 22** may be urged into an open configuration to receive tissue in jaw opening **32** between the jaw members **20, 22**.

[0065] Launch tube **28** may be advanced from its proximal end at handle **16** such that the portion of launch tube **28**, which extends distally from body **12**, is forced to rotate at hinge or pivot **30** and reconfigure itself such that the exposed portion forms a curved or arcuate shape that positions the launch tube opening perpendicularly relative to upper jaw member **22**. Launch tube **28**, or at least the exposed portion of launch tube **28**, may be fabricated from a highly flexible material

or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

[0066] Figs. 2A to 2C illustrate one method for articulating a tissue manipulation assembly into an opened and closed configuration. As shown in Fig. 2A, the assembly may be delivered into a patient while in a low-profile configuration **40**, e.g., transorally, through an endoscope, an endoscopic device, or directly. Once desirably positioned, launch tube **28** may be urged proximally via its proximal end at handle **16**. Because of jaw assembly pivot **18** and the relative positioning of upper jaw pivot **26** along lower jaw member **20** and launch tube pivot **30** along upper jaw member **22**, the proximal movement of launch tube **28** may effectively articulate upper jaw **22** into an expanded jaw configuration **42**, as shown in Fig. 2B. Proximally urging launch tube **28** may also urge lower jaw member **20** to pivot about assembly pivot **18** and form an angle, α, relative to a longitudinal axis of tubular body **12**. The opening of upper jaw **22** relative to lower jaw **20** creates jaw opening **32** for grasping or receiving tissue. Moreover, the tissue manipulation assembly may also include a stop located adjacent to jaw assembly pivot **18** or within the pivot **18** itself.

[0067] Once launch tube **28** has been urged proximally, it may be locked into place thus locking the jaw configuration as well. Moreover, having the launch tube **28** articulate the jaw members **20**, **22** in this variation eliminates the need for a separate jaw articulation and/or locking mechanism. Once the tissue has been pulled or manipulated between jaw members **20, 22**, launch tube **28** may be pushed distally to actuate the jaw members **20, 22** into a closed, grasping configuration **48**, as shown in Fig. 2C, for engagement with the tissue. As launch tube **28** is urged distally through body **12**, lower jaw member **20** may be maintained at the angle, α, relative to the tissue to further facilitate manipulation of the grasped tissue.

[0068] Launch tube **28** may further define a flexible portion **44** distally of a rigid portion **46**. Although launch tube **28** may be fabricated from different materials having differing flexibilities, it may also be fabricated from a single material, as mentioned above, where the flexible portion **44** may configured, e.g., by slotting, to allow for bending of the launch tube **28** in a plane to form a single curved or arcuate section while the rigid section **46** may extend at least partially into tubular body **12** to provide column strength to launch tube **28** while it is urged distally upon upper jaw member **22** and upon any tissue engaged thereby, as seen in the Fig. 2C.

[0069] Once the tissue has been engaged between jaw members **20**, **22**, a needle assembly may be urged through handle **16** and out through launch tube **28**. The needle assembly may pass through lower jaw member **20** via needle assembly opening **50** defined in lower jaw member **20** to pierce through the grasped tissue. Once the needle assembly has been passed through the engaged tissue, one or more tissue anchors may be deployed for securing the tissue, as described in further detail in U.S. Pat. App. Serial No. 10/955,245, which has been incorporated by reference above.

[0070] Figs. 3A and 3B show detail perspective views of the tissue manipulation assembly. As shown in Fig. 3A, lower jaw member **20** and upper jaw member **22** may be seen its open configuration **42** when the launch tube has been urged proximally. Launch tube channel **52** may also be seen defined within upper jaw member **22** for providing a space for positioning the launch tube when in the low-profile configuration. Also shown is needle assembly opening **50** defined within lower jaw member **20** for passage of the needle assembly therethrough. Fig. 3B shows the assembly in its closed jaw configuration where the launch tube has been urged distally in which it rotates about launch tube pivot **30** such that the opening the launch tube become perpendicular relative to the jaw members **20**, **22**.

[0071] Although one particular variation of the jaw members **20**, **22** is shown, this is not intended to be limiting in jaw member configuration or operation. Other variations may include various placement of the jaws relative to one another, alternative configurations for articulating the jaw members, alternative configurations for the launch tube placement, etc. Other variations are intended to be within the scope of this disclosure.

[0072] As mentioned above, a needle deployment assembly **60** may be deployed through the assembly **10** by introducing needle deployment assembly **60** into the handle **16** and through tubular body **12**, as shown in the assembly view of Fig. 4, such that the needle assembly **66** is advanced from the launch tube and into or through approximated tissue. Once the needle assembly **66** has been advanced through the tissue, the anchor assembly **68** may be deployed or ejected. Anchor assembly **68** is normally positioned within the distal portion of tubular sheath **64**, which extends from needle assembly control or housing **62**. Once the anchor assembly **68** has been fully deployed from sheath **64**, the spent needle deployment assembly **60** may be removed from assembly **10** and another needle deployment

assembly may be introduced without having to remove assembly **10** from the patient. The length of sheath **64** is such that it may be passed entirely through the length of tubular body **12** to enable the deployment of needle assembly **66** into and/or through the tissue.

[0073] Fig. 5A shows a detailed assembly view of the needle deployment assembly **60** from Fig. 4. In this variation, elongate and flexible sheath or catheter **64** may extend removably from needle assembly control or housing **62**. Sheath or catheter **64** and housing **62** may be interconnected via interlock **70** which may be adapted to allow for the securement as well as the rapid release of sheath **64** from housing **62** through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. Needle body **72**, which may be configured into any one of the variations described above, may extend from the distal end of sheath **64** while maintaining communication between the lumen of sheath **64** and needle opening **74**.

[0074] Elongate pusher **76** may comprise a flexible wire or hypotube which is translationally disposed within sheath **64** and movably connected within housing **62**. A proximally-located actuation member **78** may be rotatably or otherwise connected to housing **62** to selectively actuate the translational movement of elongate pusher **76** relative to sheath **64** for deploying the anchors from needle opening **74**. Anchor assembly **68** may be seen positioned distally of elongate pusher **76** within sheath **64** for deployment from sheath **64**. Needle assembly guides **80** may also be seen protruding from housing **62** for guidance through the locking mechanism described above. Fig. 5B shows an exploded assembly view of the needle deployment assembly **60** from Fig. 5A. As seen, sheath **64** may be disconnected from housing **62** via interlock **70** to reveal the elongate pusher **76** connected to housing **62** and the distal and proximal anchors **82**, **84**, respectively, of anchor assembly **68**.

[0075] With respect to the anchor assemblies, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, the tissue anchor variations may also include "T"-type anchors while other variations may include reconfigurable "basket"-type anchors, which may generally comprise a number of configurable struts or legs extending between at least two collars or support members or reconfigurable mesh structures extending between the two collars. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different

anchor types may be used in an anchor assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0076] Other variations for the needle assemblies and for the anchors are described in further detail in U.S. Pat. App. Serial No. 10/955,245, which has been incorporated by reference above.

[0077] In operation when manipulating and securing tissue within a patient's body, a separate elongate shaft having a tool on or near the distal end of the shaft may be utilized in conjunction with the tissue manipulation assembly **14**. Such tools are generally utilized in endoluminal procedures where the tools are delivered through an endoscope. Generally, several different tools may be utilized for performing a procedure endoluminally.

[0078] As illustrated in Fig. 6, one such example is shown in which a shape-lockable endoscopic assembly **90** may be advanced into a patient's stomach **S** per-orally and through the esophagus **E**. Such an endoscopic assembly **90** may generally comprise an endoscopic device which may have a distal portion which may be articulated and steered to position its distal end anywhere within the stomach **S**. Once desirably configured, assembly **90** may then be locked or rigidized to maintain its shape or configuration to allow for procedures to be performed on the tissue utilizing any number of tools delivered through the assembly **90**. Shape-lockable assembly **90** and its variations are described in further detail in U.S. Pat. App. Serial No. 10/734,562 filed December 12, 2003, which is incorporated herein by reference in its entirety.

[0079] Shape-lockable assembly **90** may be generally comprised of shape-lockable endoscopic body **92** having an articulatable distal portion **96**. The endoscopic body **92** may define at least first and second lumens **98, 100**, respectively, through the endoscopic body **92** through which one or more tools may be deployed into the stomach **S**. Additional lumens may be provided through shape-lockable endoscopic body **92**, such as a visualization lumen **101**, through which an endoscope may be positioned to provide visualization of the region of tissue. Alternatively, an imager such as a CCD imager or optical fibers may be provided in lumen **101** to provide visualization. An optional thin wall sheath **94** may be disposed through the patient's mouth, esophagus **E**, and possibly past the gastroesophageal junction **GEJ**

into the stomach **S**. Shape-lockable body **92** may be advanced through esophagus **E** (and through sheath **94**, if utilized) and into stomach **S** while disposed in a flexible state.

[0080] Distal steerable portion **96** of endoscopic body **92** may be then articulated to an orientation, e.g., whereby distal portion **96** facilitates engagement of tissue near and/or inferior to the patient's gastroesophageal junction **GEJ**. Accordingly, distal steerable portion **96** may comprise a number of steering features, as described in further detail in U.S. Pat. App. Serial No. 10/734,562, incorporated above. With distal steerable portion **96** disposed in a desired configuration or orientation, endoscopic body **92** may be reversibly shape-locked to a rigid state such that the endoscopic body **92** maintains its position within the stomach **S**. Various methods and apparatus for rigidizing endoscopic body **92** along its length are also described in further detail in U.S. Pat. App. Serial No. 10/734,562, incorporated above.

[0081] Fig. 6 shows tissue manipulation assembly **14** having been advanced through first lumen **98** and a tissue engagement member **102** positioned upon flexible shaft **104** advanced through second lumen **100**. As the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, tissue engagement member **102** may be advanced into contact with the tissue and preferably engages the tissue **F** such that when the tissue engagement member **102** is pulled proximally to draw the engaged tissue **F** between the jaw members **20, 22** of tissue manipulation assembly **14**, at least the muscularis tissue layer and the serosa layer is drawn into tissue manipulation assembly **14**.

[0082] As tissue manipulation assembly **14** may be utilized to grasp and secure the engaged tissue, any number of tools may be utilized with tissue manipulation assembly **14**, e.g., through shape-lockable endoscopic body **92**, to engage and manipulate the tissue of interest relative to tissue manipulation assembly **14**. Fig. 7 illustrates tissue manipulation assembly **14** upon flexible body **12** with handle **16** and examples of various tools which may be used in combination with tissue manipulation assembly **14**.

[0083] Turning to Fig. 7, one example of a tool utilizable in combination with tissue manipulation assembly **14** is shown in tissue engagement member **102** as a

tissue piercing helix or corkscrew structure upon flexible shaft **104** (as shown in Fig. 6). Tissue engagement member **102** may be rotated about its longitudinal axis to engage the tissue of interest by rotating handle **106** located on the proximal end of flexible shaft **104**. Alternatively, a tool having aggressive tissue graspers **108** positioned upon flexible shaft **110** and articulatable via handle **112** may be utilized in combination with tissue manipulation assembly **14**. Another alternative tool may be tissue graspers **114** positioned upon flexible shaft **116** and articulatable via handle **118**. Tissue graspers **114** may have atraumatic grasping surfaces. In yet another alternative, an endoscope **122** having optical fibers or imager **120** may be utilized for providing visualization. Endoscope **122** may be articulated via handle **124** at its proximal end.

[0084] The examples of the various tools as shown and described are intended merely to be illustrative of the range of tools which may be usable with assembly **14** and are not intended to be limiting in any manner. Any number of other tools may be accordingly utilized and are intended to be within the scope of this disclosure.

[0085] An example of performing an endoluminal tissue manipulation and securement procedure utilizing tissue manipulation assembly **14** in combination with a separate tissue grasping tool within, e.g., a patient's stomach, is illustrated in Figs. 8A to 8D. As shown in Fig. 8A, once shape-lockable endoscopic body **92** has been introduced into the patient, e.g., trans-orally, trans-anally, percutaneously, etc., and desirably positioned relative to a tissue region of interest **130**, endoscopic body **92** may be rigidized to maintain its configuration within the patient body. Alternatively, it may be left in a flexible state during the procedure.

[0086] The tissue region of interest **130** as well as the procedure may be visualized through visualization lumen **101** or a separate imager, as described above. In either case, tissue manipulation assembly **14** and tissue engagement member **102** may be advanced distally out from endoscopic body **92** through their respective lumens **98, 100**. Tissue engagement member **102** may be advanced into contact against the tissue surface, as shown in Fig. 8A, and then rotated via its proximal handle until the tissue is engaged. The engaged tissue **F** may be pulled proximally relative to endoscopic body **92** and tissue manipulation assembly **14** may be actuated via its proximally located handle into an open expanded jaw configuration for receiving the engaged tissue **F**, as shown in Fig. 8B.

[0087] Alternatively, once the tissue **F** has been engaged, tissue manipulation assembly **14** may be advanced distally in its open configuration onto the engaged tissue. In yet another variation, tissue engagement member **102** may be omitted entirely and tissue manipulation assembly **14** may be utilized alone to grasp onto the tissue region of interest **130**. In yet another alternative, a second tissue manipulation assembly may be used in combination with tissue manipulation assembly **14**.

[0088] Turning back to Fig. 8B, tissue manipulation assembly **14** may be articulated to receive the engaged tissue **F**. As shown in Fig. 8C, once engaged tissue **F** is positioned between jaw members **20, 22**, the launch tube may be urged proximally to actuate upper jaw member **22** to grasp or clamp upon the tissue **F**. Tissue engagement member **102** may be retracted from the tissue **F** or it may be left within the tissue while tissue manipulation assembly engages and secures the tissue **F**.

[0089] Fig. 8D shows a partial cross-sectional view of the tissue **F** while engaged to tissue manipulation assembly **14**. Tissue engagement member **102** has been omitted from this view only for the sake of clarity. As mentioned above, member **102** may be left remaining in the tissue **F**, disengaged from tissue **F**, or disengaged and removed entirely from endoscopic body **92**, if so desired, and another tool may be advanced through lumen **100** to facilitate the procedure. Once jaw members **20, 22** have been actuated to clamp or grasp upon tissue **F** by the launch tube, the launch tube may be automatically positioned into its anchor deployment configuration. The needle assembly may then be urged via manipulation from its proximal end at handle **16** through the launch tube to pierce preferably through a dual serosa layer through engaged tissue **F** and past lower jaw member **20**. As described above, the engaged tissue **F** positioned between the jaw members **20, 22** is desirably engaged such that the needle body **72**, when urged through the tissue **F**, is disposed through the muscularis and/or serosa layers of the engaged tissue **F**. Once needle body **72** has passed through tissue **F**, one or more expandable tissue anchors may be ejected from needle body **72** through needle opening **74**.

[0090] Because needle body **72** may penetrate the tissue wall twice, it exits within the body lumen if utilized within, e.g., the stomach, thus reducing the potential for injury to surrounding organs. As described above, needle body **72** may define needle lumen or opening **74** through which an expandable anchor, e.g., distal anchor **82** and/or proximal anchor **84**, may be situated during deployment and positioning of the assembly. A single suture or flexible element **132** (or multiple suture elements)

may connect distal anchor **82** and proximal anchor **84** to one another and end in terminal loop **134**. For instance, element **132** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0091] Once distal anchor **82** has been ejected, needle body **72** may be urged proximally back through tissue **F**, where proximal anchor **84** may then be ejected from needle body **72** with suture **132** still connecting the two anchors **82**, **84** through tissue **F**. Alternatively, tissue manipulation assembly **14**, with suture **132** still depending therefrom, may be disengaged from tissue **F** and the procedure may be repeated at a second region of tissue where proximal anchor **84** may then be ejected.

[0092] Fig. 9A shows one variation where a single fold **F** may be secured between proximal anchor **82** and distal anchor **84**. With both anchors **82**, **84** disposed externally of the launch tube and suture **132** connecting the two, proximal anchor **84** may be urged into contact against tissue **F**. As the anchors are urged against tissue fold **F**, distal anchor **82** or a portion of suture **132** may be configured to provide any number of directionally translatable locking mechanisms **136** which provide for movement of an anchor along suture **132** in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture **132**.

[0093] Fig. 9B shows another variation where a at least two folds $\mathbf{F_1}$ and $\mathbf{F_2}$ may be secured between proximal anchor **82** and distal anchor **84**. After the anchors have been ejected from needle body **72**, the anchors may be approximated towards one another over suture **132** thus bringing folds $\mathbf{F_1}$ and $\mathbf{F_2}$ towards one another. Although a single tissue fold and a dual fold are shown in these examples, any number of folds or tissue ridges may be created using the tools disclosed herein. Moreover, these examples are merely intended to be illustrative and not limiting in any way. In either case, it may be generally desirable to form the tissue folds such that serosa-to-serosa contact **138** occurs between the layers of secured tissue, although this may not be necessary.

[0094] Various examples of cinching devices and methods which may be utilized with the tools and devices herein are described in further detail in U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated herein above.

[0095] In using the launch tube as a jaw actuation mechanism, other variations of the launch tube may be utilized to ensure sufficient strength and force transmission

in tissue manipulation assembly **14** for jaw member actuation. One such example is shown in the perspective view of Fig. 10A, which shows launch tube **44** having a number of reinforcement members or bars **140** aligned along one or both sides of the launch tube to provide for additional column strength. Each of the reinforcement members **140** may be pivotally attached to launch tube **44** via pivot members **144** rotatably secured within pivot channels **142**, as seen in the launch tube cross-section in Fig. 10B. Moreover, each of the pivot members **144** may define cooperating adjacent members relative to one another while maintaining contact to allow for the transmission of force between the members **144**. Pivot members **144** may be positioned along the length of the exposed launch tube or a portion of the launch tube; moreover, a single side of the launch tube may have pivot members **144** attached thereto. Alternatively, rather than utilizing pivot members, portions of the launch tube itself may be simply thickened to increase its column strength and force transmission capabilities.

[0096] In another variation, as shown in Fig. 11A and the launch tube cross-section in Fig. 11B, a pull wire **152** may be routed through tubular body **12** and launch tube **44** through a pull wire lumen **150** to provide a launch tube and jaw actuation mechanism separate from the launch tube actuation itself. Pull wire **152** may be manipulated via its proximal end at handle **16** by pulling or pushing pull wire **152** to actuate launch tube **44** and/or jaw members **20, 22**. Alternatively, as seen in Fig. 12, pull wire **152** may be routed through tubular body **12** and connected directly to launch tube **44** at pull wire attachment point **154** rather than routing it through the launch tube. Again, manipulation of pull wire **152** may be utilized to articulate the launch tube configuration as well as jaw member articulation.

[0097] Referring now to Figs. 13 and 14, a variation of the anchor assembly and the needle deployment assembly is described. As with previously described needle deployment assembly **60**, assembly **60'** comprises needle assembly control or housing **62**, tubular sheath **64** and needle assembly **66** having needle body **72** with opening **74**. Elongate pusher **76** is configured for translation within sheath **64** via actuation member **78**. Pusher **76** illustratively comprises a hypotube having lumen **77** defined therethrough.

[0098] In the variation of Figs. 13 and 14, locking mechanism **136** of anchor assembly **68'** is disposed proximal of proximal anchor **84**, and the anchor assembly is positioned within the distal portion of tubular sheath **64**, such that the distal region of

pusher **76** abuts locking mechanism **136**. Suture or flexible element **132'** comprising distal knot or protrusion **133** extends proximally from the knot in a manner that connects distal anchor **82**, proximal anchor **84** and locking mechanism **136**. Element **132'** then further extends through lumen **77** of pusher **76** to a proximal region of assembly **60'** such that element **132'** may be manipulated by a medical practitioner from outside a patient. The medical practitioner may, for example, engage previously described suture loop **134**, or may engage some other control element **134'**, such as a ring or handle, disposed at the proximal end of suture element **132'**. As will be apparent, in another variation, element **132'** may extend to the proximal region of assembly **60'** alongside pusher **76** rather than within a lumen of the pusher.

[0100] With reference to Figs. 15, a method of using anchor assembly **68'** and needle deployment assembly **60'** is described. For the purposes of illustration, the assemblies are shown securing tissue without use of a tissue manipulation assembly. However, it should be understood that the assemblies alternatively may be used in combination with a tissue manipulation assembly, such as previously described tissue manipulation assembly **14** of assembly **10**.

[0101] In Fig. 15A, needle deployment assembly **60'** has been positioned in proximity to approximated tissue **T**. The assembly is advanced such that needle assembly **66** pierces the tissue and is advanced through and across the tissue, as in Fig. 15B. Pusher **76** is advanced within the lumen of sheath **64** via actuation member **78**, such that distal anchor **82** of anchor assembly **68'** is ejected through opening **74** of needle body **72** of needle assembly **66** on the distal side of approximated tissue **T**. Needle deployment assembly **60'** and pusher **76** then are retracted such that the pusher and needle assembly **66** again are disposed on the proximal side of the approximated tissue, as in Fig. 15C. Next, pusher **76** is distally advanced relative to sheath **64** to eject proximal anchor **84** from the sheath.

[0102] In Fig. 15D, with the proximal and distal anchors of anchor assembly **68'** disposed on either side of the approximated tissue, the anchor assembly is cinched by retracting control element **134'** relative to needle deployment assembly **60'**. Pusher **76** abuts locking mechanism **136** and urges it distally during proximal retraction of element **134'**, which shortens the length of suture element **132'** disposed between distal anchor **82** and proximal anchor **84**, thereby cinching anchor assembly **68'**. Locking mechanism **136** ensures that the anchors remain cinched by resisting

distal passage of element **132'** through the mechanism, thereby resisting subsequent separation of the proximal and distal anchors.

[0103] With anchor assembly **68'** cinched, pusher **76** is retracted relative to sheath **64** such that needle assembly **66** engages suture element **132'**, as in Fig. 15E. The needle assembly cuts the suture proximal of locking mechanism **136**, as in Fig. 15F. The medical practitioner may facilitate cutting of the suture element by manipulating control element **134'** of anchor assembly **68'** and/or by manipulating needle assembly control **62** of needle deployment assembly **60'**.

[0104] Referring now to Fig. 16, a variation of the suture element of anchor assembly **68'** is described. In Fig. 16, suture element **132''** comprises segment **135** of reduced integrity. The segment may for example, comprise fewer suture strands or may be reduced in integrity via chemical, electrical, thermal or physical processing, etc. Segment **135** may locally reduce the tensile strength of element **132''** to a desired threshold. When used to cinch anchor assembly **68'** in combination with anchor deployment assembly **60'**, the segment may obviate a need to cut the suture with needle assembly **66** after cinching of the anchor assembly. Specifically, the anchor assembly may be cinched to a desired tension after which segment **135** plastically deforms and snaps, leaving the anchor assembly cinched and in place.

[0105] With reference to Fig. 17, a variation of the needle assembly of needle deployment assembly **60'** is described. Needle body **72'** of needle assembly **66'** may comprise one or more recessed cut-outs **73** having sharpened edges **E** for cutting the suture element. After cinching of anchor assembly **68'**, the suture element may be snagged within a cut-out **73** and cut by the sharpened edge of the cut-out.

[0106] Referring now to Fig. 18, alternative control mechanisms for needle deployment assembly **60'** are described. Actuation member **78'** for controlling pusher **76** may be integrated with needle assembly control **62'**, such that the actuation member is advanceable in controlled increments relative to the needle assembly control via detents **63** of the needle assembly control that coact with actuation member **78'**.

[0107] With reference to Figs. 19, another variation of the anchor assembly and needle deployment assembly is shown. Control element **134'** of anchor assembly **68'** is coupled to or abuts needle assembly control **62'** of needle deployment assembly **60'**. When distal anchor **82** of anchor assembly **68'** is disposed on the distal side of approximated tissue **T**, as in Fig. 19A, the proximal and distal ends of suture element

132' are constrained. Thus, as seen in Figs. 19A and 19B, advancement of pusher **76** via actuation member **78'** advances both proximal anchor **84** and locking mechanism **136** of anchor assembly **68'**. This causes the anchor assembly to be progressively cinched as the proximal anchor is advanced. Once the anchor assembly has been ejected from sheath **64**, as in Fig. 19B, and adequately cinched, as in Fig. 19C, suture element **132'** may be cut proximal of the locking mechanism, e.g., with needle assembly **66** as described previously.

[0108] Referring to Figs. 20, a variation of the needle deployment assembly is described. Pusher **76'** comprises suture ports **79** through which suture element **132** of anchor assembly **68'** is routed. As seen in Fig. 20A, with pusher **76'** disposed within tubular sheath **64** of needle deployment assembly **60'**, suture element **132'** passes out of the pusher between the suture ports and is disposed between the pusher and the interior wall of the tubular sheath. As seen in Fig. 20B, when pusher **76'** is advanced through and distal of needle assembly **66**, e.g., to eject proximal anchor **84** of anchor assembly **68'** from the needle deployment assembly and/or to cinch the anchor assembly, the section of suture element **132'** between the suture ports is exposed. Subsequent retraction of the pusher relative to the needle assembly causes the section of exposed suture to contact the sharpened edge of needle assembly **66**, thereby severing suture element **132'** as in Fig. 20C.

[0109] Turning now to Figs. 21, another variation of the needle deployment assembly is shown. In this variation, suture element **132'''** may form a terminal loop **158** through which a release suture or wire **156** may be passed. Release suture or wire **156** may be routed through the length of the needle deployment assembly and through pusher **76**, as described above, and both release suture or wire **156** and terminal loop **158** may both be situated within pusher **76**, as shown in Fig. 21A. After deployment of the anchors into tissue and cinching of the assembly, as described above, one end of release suture or wire **76** may be pulled or tensioned proximally in the direction shown by arrow **162**, as in Fig. 21B. This pulling may draw a terminal end of release suture or wire **156** through pusher **76** until terminal loop **158** of suture element **132'''** has been released therefrom, as shown in Fig. 21C.

[0110] In yet another variation shown in Fig. 22A, terminal loop **158** of suture element **132'''** may be seen restrained within pusher **76** via reconfigurable hook **164** of release wire **156'**. Here, release wire **156'** may be fabricated from a shape memory or superelastic alloy material, such as Nitinol, which has been preformed to

reconfigure its terminal end from a hook **164** configuration to a straightened or opened configuration once released from the constraints of pusher **76**. Thus, after deployment and cinching of the anchor assembly, release wire **156'** may be advanced distally through pusher **76**, as shown in Fig. 22B, until reconfigurable hook **164**, which is retained in a hooked or obstructive configuration within the lumen of pusher **76**, has been advanced out of pusher **76**. Once free from the constraints of the lumen, hook **164** may reconfigure itself into an opened or straightened configuration to thereby release terminal loop **158** of suture element **132'''**, as shown in Fig. 22C. Hook **164** having released terminal loop **158**, may then be withdrawn proximally back into pusher **76** in its straightened configuration.

[0111] In another variation shown in Fig. 23A, a terminal end of suture element **132'''** may have an obstructive or enlarged element **160**, e.g., a knot, formed thereon. The terminal end of suture element **132'''** with obstructive element **160** may be looped around release suture or wire **156** and retained within the lumen of pusher **76**. After anchor deployment and cinching, release suture or wire **156** may be drawn distally with looped obstructive element **160** retained securely thereto, as shown in Fig. 23B, until obstructive element **160** and release suture or wire **156** have been advanced out of pusher **76**. Once free from the constraints of the pusher lumen, obstructive element **160** may be released from release suture or wire **156**, as shown in Fig. 23C, to thus release suture element **132'''**.

[0112] Turning now to the alternative variation shown in Figs. 24A to 24C, suture element **132'** may be passed through pusher **76''** having heating element assembly **170** disposed upon the distal end of pusher **76''**. Heating element assembly **170** may generally comprise a heating element **172**, e.g., a resistive metallic conductor such as nichrome, and an insulating element **174** disposed distally of heating element **172**, as shown in Fig. 24A. In use, pusher **76''** may be urged distally from needle assembly **66** to cinch the anchors against the tissue surface, as described above. With heating element assembly **170** disposed externally or internally of needle assembly **66**, heating element **172** may be powered such that its increase in temperature surpasses the melting point of the suture element **132'** passing therethrough, as shown in Fig. 24B. The melting point of the suture **132'** will vary depending upon the type of suture utilized.

[0113] Insulating element **174**, which may be made from any number of electrically and thermally non-conductive insulating materials such as ceramics,

polyimides, etc., may be disposed distal of heating element **172** to prevent inadvertent contact against the tissue by heating element **172** while it is heated although insulating element **174** may be omitted entirely from the assembly **170**. As heating element **172** is heated, the portion of suture **132'** adjacent to element **172** will be melted and subsequently cut forming melted suture ends **176, 176'** on their respective terminal ends of suture element **132'** and the remaining suture length **178**, as shown in Fig. 24C.

[0114] Fig. 25A shows a partial cross-sectional detail view of the heating element assembly **172** disposed upon the distal end of pusher **76''**. As shown, heating element **172** and insulating element **174** may be positioned adjacent to one another. A covering, coating, or insulating layer **180** (e.g., heatshrink made from FEP, PEEK, Teflon, polyimide, etc.) may be disposed over the heating assembly **170** entirely or at least partially such that heating element **172** is completely encapsulated and insulated from surrounding tissue except for the inner exposed surface within lumen **188**, where it may come in contact with or in proximity to the suture for severing the suture element **132'**. Electrically conductive wires **182**, which may be embedded along the length of pusher **76''**, may be routed through heating element assembly **170** via wire contact lumens **184, 186** to not only provide power to heating element **172**, but also to provide structural support in maintaining the position of heating element assembly **170** upon the distal end of pusher **76''**. Alternatively, the elements **172, 174** of assembly **170** may be attached to one another utilizing any number of mechanical fasteners, e.g., adhesives, threaded connections, interference fitting, etc.

[0115] Fig. 25B shows a partial assembly of pusher **76''** and elements **172, 174** in an exploded view (cover **180** has been omitted for clarity). Wires **182** may pass through heating element assembly **170**, along pusher **76''**, and proximally into electrical contact with a controller and/or power supply **190** via a standard removable connector or through a direct electrical connection. Controller/power supply **190** may be located externally of the patient as a device separate from pusher **76''** and within or outside a sterile surgical field around the patient. Alternatively, the power supply **190** may be integrated with a proximal portion of the pusher **76''**. An actuator **192**, such as a foot-operated pedal or hand-operated switch, may be electrically connected via connector **194** to controller/power supply **190** for controlling the actuation of the heating element assembly **170**.

[0116] An alternative heating assembly is shown in Figs. 26A and 26B. Fig. 26A illustrates a partial side view of pusher **76'''** having a heating assembly **200** disposed upon the distal end of pusher **76'''** with suture element **132'** routed therethrough. Heating assembly **200** may generally comprise an insulative body **202** having a circumferentially-defined depression **204**. One or more slots, grooves, or openings **206** extending radially through body **202** may be defined within the depression **204** such that an electrically resistive wire **208** which is coiled, wrapped, or otherwise wound around body **202** along depression **204** may effectively transfer heat generated by wire **208** through the one or more openings **206** to melt and separate the portion of suture element **132'** positioned within lumen **210** of body **202**, as shown in Fig. 26B. A portion of coiled wire **208** may be optionally potted with an insulating material, such as epoxy, within depression **204** to retain the wire **208** in place as well as to insulate the wire **208** from surrounding tissue.

[0117] The heating assembly **200** may be positioned upon the distal end of pusher **76'''** utilizing any of the methods described above or generally known. Moreover, conductive wires **182** may be routed along or through pusher **76'''** and connected via, e.g., a connector, to controller and/or power supply **190**, which may be connected to a foot pedal, hand switch, or other actuator **192**, as described above.

[0118] Yet another variation is shown in the partial cross-sectional view of pusher **76''''** of Fig. 27A, which shows an alternative heating assembly **220** having a resistive wire or element **224** encased within a casing or housing **222** which forms a portion of the pusher wall. Although the housing **222** is shown near or at the distal end of pusher **76''''**, housing **222** may also be located along the pusher wall proximal to the distal end. Fig. 27B shows a cross-section of a portion of pusher **76''''** and housing **222**. As shown, resistive wire **224** may be positioned through housing **222** such that heat from the wire **224** may melt or sever the portion of suture **132'** adjacent to or in contact with housing **222**. As above, wire **224** may be connected to a proximally located controller/power supply **190**.

[0119] In the variations described above utilizing a heating element to sever the suture, the heating elements may be powered in a continuous manner until shut off by the user. Alternatively, the power may be configured to operate for a pre-determined period of time once turned on before automatically shutting off. In yet another alternative, the power may pulse in a cyclical manner such that the heating element is heated only for a specified period of time before automatically shutting off

for a set period. This cycle may be repeated until the device is turned off. Such features may be incorporated as part of the instrument as a fail-safe feature, is so desired.

[0120] In one example of a cyclical timing profile shown in Fig. 28, once the actuator has been turned on to heat the heating element to sever the suture, the controller connected to the heating element may be configured to pulse the power **230** for a set period of time, Δt, e.g., 1 to 2 seconds. The power may then automatically shut off **234** for a set period of time, Δd, e.g., 1 to 5 seconds; then the power may be automatically turned on again **232** and then off again **236**. This may occur for a set number of cycles or for a set period of time before the device is completely shut off or until the user completely shuts the power off upon suture separation.

[0121] In yet another variation for effecting suture separation, an alternative pusher **240** is shown in cross-section in Fig. 29A. Here, pusher **240** may have a needle body **242** with a circumferential cutting edge **244** defined at its distal end, similar to a coring needle, and a lumen **246** defined therethrough for passage of suture element **132'**. Once the tissue anchors have been deployed into the tissue, cutting edge **244** may be used to cut or sever suture element **132'** passing through pusher **240** and needle body **242**. During tissue anchor cinching of the locking mechanism **136** against the tissue anchor, as described above, cutting edge **244** may be optionally tapered to otherwise sized, without obstructing lumen **246**, to allow cutting edge **244** to become seated within the locking mechanism **136**. Thus, as pusher **240** and needle body **242** abuts against locking mechanism **136** to urge it distally along suture element **132'**, cutting edge **244** may avoid direct contact against locking mechanism **136** so as to prevent dulling of cutting edge **244**.

[0122] Alternatively or additionally, locking mechanism **136** itself may be coated or otherwise covered with a heatshrink material or other soft polymeric material, at least over a proximal portion, so as to present an atraumatic surface to cutting edge **244**. In a further alternative, an intermediate element (not shown) made of a suitably soft material, e.g., polymers, may be disposed between needle body **242** and locking mechanism **136** to function as a temporary bumper.

[0123] In use, once the tissue anchors and locking mechanism **136** have been desirably deployed, pusher **240** and needle body **242** may be extended and the suture element **132'** passing through needle body **242** may be simply severed by pulling or urging suture element **132'** against cutting edge **244** until separation occurs. In

another alternative method for separating suture element **132'**, Figs. 30A to 30C illustrate another method utilizing the tissue manipulation assembly described above. Once the tissue anchors and locking mechanism have been deployed from pusher **240** and launch tube **28**, as shown in Fig. 30A, lower jaw **20** and upper jaw **22** of the tissue manipulation assembly may be actuated to clamp upon suture element **132'**, as shown in Fig. 30B.

[0124] The suture element **132'** still disposed through pusher **240**, which is positioned within the launch tube, may be tensioned at least partially, e.g., by pulling on a proximal end of suture element **132'**. With suture element **132'** tightly secured between jaw members **20, 22**, pusher **240** and needle body **242** may be urged distally through launch tube **28** until cutting edge **244** severs the portion of suture element **132'** held tightly by jaw members **20, 22**, as shown in Fig. 30C. The tissue manipulation assembly may then be removed from the patient or manipulated to another portion of the body for treatment.

[0125] In yet another variation for suture separation, the tissue manipulation assembly may again be utilized by incorporating a suture cutting element along either or both jaw members **20, 22**. For example, as shown in Fig. 31A, a cutting element, e.g., a blade, energizable wire, etc., may be positioned along an upper region **250** of upper jaw **22**, or a cutting element may be positioned along a lower region **252** of lower jaw **20**, or both may be utilized in combination with one another. Figs. 31B and 31C show partial side views of upper jaw **22** and deployed launch tube **44** and pivot **30**. A cutting blade, for instance, may be positioned adjacent to the launch tube **44** and angled at various directions relative to where the suture exits the launch tube such that the blade does not obstruct deployment of the tissue anchors or suture.

[0126] Placement of the cutting blade, however, is such that the upper jaw **22** may be manipulated to bring the suture element into contact with the blade for severing the suture. Fig. 31B shows blade **254** angled such that cutting edge **256** is directed away from the launch tube **44** opening. Alternatively, blade **154'**, in Fig. 31C, shows another example where blade **254'** may be angled such that cutting edge **256'** is directed towards the launch tube **44** opening.

[0127] Rather than integrating a cutting blade along upper jaw **22**, one or more cutting blades may instead be incorporated along lower jaw **20**. As shown in the example of Fig. 31D, a partial top view of lower jaw **20** is shown with an optional cutting blade **258** with cutting edge **260** integrated near a proximal portion of needle

assembly opening **50** defined in lower jaw member **20**. Another alternative is shown in Fig. 31E where a cutting blade **258'** having a cutting edge **260'** may be integrated along a side portion of opening **50**. These examples shown are intended to be illustrative and not limited and one or more cutting blades may be integrated along other surfaces of the tissue manipulation assembly as desired. Moreover, cutting blades may be integrated along the lower jaw, upper jaw, or both if so desired. Furthermore, the cutting blades may additionally be energized in further variations to facilitate severing the suture.

[0128] Turning now to Fig. 32, needle deployment assembly **270** is shown as a variation which is similar to that illustrated above in Figs. 15 and 23. In this example, needle deployment assembly **270** is configured to endoluminally deploy tissue anchors as well as cinch and release anchor assemblies to secure one or more tissue folds. Assembly **270** generally comprises a needle assembly control or housing **272** which may be configured into an elongate shape having a guide track **274** defined therealong. A first locking position **276** may be defined at a proximal end of guide track **274** and a second locking position **278** may be defined at a distal end of guide track **274** where each locking position **276, 278** may be configured, e.g., as a cut-out or transverse section of guide track **274**, within which a slidable actuation member **286** (described below) may be parked or locked temporarily.

[0129] Retraction control element **280** may be removably connected via a coupling mechanism such as a threaded connection **282** to the proximal end of control or housing **272** and tubular catheter or sheath **64** may be coupled via sheath attachment **284** at the distal end of control or housing **272**. Needle assembly**66**, including needle body **72** having needle opening **74**, may be attached to the distal end sheath **64**, as described above.

[0130] Needle deployment assembly **270** may operate in a similar manner as the variation described above where once needle body **72** has pierced through approximated tissue **T**, distal anchor **82** may be deployed through needle opening **74** on a distal side of tissue **T**, as shown in Fig. 33A. Suture element **132** may be seen connecting distal anchor **82** through the pierced tissue **T** and through needle opening **74**. A terminal distal end of suture element **132** may define a distal knot or protrusion **133** to prevent distal anchor **82** from sliding off suture **132**. Distal anchor **82**, which is originally positioned within sheath **64** proximal or adjacent to needle body **72**, may be urged distally through needle opening **74** by sliding actuation member **286** from its

parked position in first locking position **276** distally along guide track **274** to a mid-point location. Actuation member **286** may be connected to slider carriage **290** translatably positioned within housing lumen **298** in control or housing **272**, as shown in Fig. 33B.

[0131] Slider carriage **290** may be connected to pusher tube **294**, which may comprise a hollow tubular member, such as a hypotube, extending at least partially through control or housing **272** and which may extend partly through sheath **64**. A distal end of pusher tube **294** may in turn be connected via coil attachment **308** to pusher coil body **296** which may extend through sheath **64** proximal to an anchor assembly disposed within the distal portion of sheath **64**. Pusher coil body **296** may be comprised of a tightly-wound coiled body which provides columnar support when pushed or pulled through sheath **64** and which is sufficiently flexible to enable pusher coil body **296** to conform to tortuous configurations. A wire lumen **292** may extend through carriage **290**, pusher tube **294**, and pusher coil body **296** within which a looped release suture or wire **156** may extend from retraction control member **280** to a cinchable anchor assembly positioned within a distal portion of sheath **64**.

[0132] A stop **300** may be crimped or otherwise fixedly positioned along a length of release suture or wire **156** within housing or control **272** with a separate plug mechanism **302** slidably positioned along suture or wire **156** proximal to stop **300**. Plug **302** may have a plug body **304** with one or more expandable arms **306** extending distally therefrom, the distal ends of which are temporarily locked within a proximal opening of lumen **292**, as illustrated in Fig. 33B. With expandable arms **306** temporarily locked in carriage **290** and encompassing stop **300**, when actuation member **286** is pushed distally along guide track **274**, carriage **290** is forced distally to urge pusher tube **294** and pusher coil body **296** through sheath **64**. Stop **300** is also urged distally along with carriage **290** by plug mechanism **302**, which in turn enables the distal portion of looped suture or wire **156** to translate distally with pusher coil body **296** to push the distal anchor **82** from needle body **72**, as shown in Fig. 33C. The proximal terminal end **310** of suture element **132** may be passed at least partially through looped suture or wire **156** within pusher coil body **296** such that when suture end **310** is withdrawn within pusher coil body **296** by suture or wire **156**, suture end **310** is fixedly retained and prevented from inadvertently releasing or unwinding by the tortuous looped path to prevent the accidental release of one or more anchors **82**, **84** from needle body **72**.

[0133] Once the distal anchor **82** has been released on a distal side of tissue **T**, proximal anchor **84** may further be released on a proximal side of tissue **T** by further urging actuation member **286** distally along guide track **274** until actuation member **286** has reached the terminal end of track **274**, where it may be locked into the second locking position **278**. Pushing actuation member **286** along track **274** may urge the distal end of pusher coil body **296** distally until it is adjacent to or distal of needle body **72**, thereby forcing proximal anchor **84** and locking mechanism **136** from needle opening **74**, as illustrated in Fig. 34A. Fig. 34B illustrates the distal movement within control or housing **272** of stop **300** and plug body **304** attached to carriage **290** via expandable arms **306**. Fig. 34C illustrates the corresponding distal translation of pusher coil body **296** and release suture or wire **156** through needle opening **74** to urge proximal anchor **84** and locking mechanism **132** therethrough. Terminal suture end **310** is still fixedly retained within pusher coil body **296** by release suture or wire **156**.

[0134] To approximate the anchors **82, 84** towards one another and secure the plicated tissue **T**, retraction control element **280** may be de-coupled or unscrewed via attachment **282** from the proximal end of control or housing **272**, as shown in Fig. 34A, and then pulled proximally or tensioned, as shown in Fig. 35A, to pull release suture or wire **156** proximally relative to carriage **290**, pusher tube **294**, pusher coil body **296**, and housing **272**. As release wire **156** is pulled, stop **300** is pulled proximally, which in turn may urge plug body **304** proximally relative to the stationary carriage **290**. As the plug mechanism is forced proximally, expandable arms **306** may become released from the proximal end of carriage **290** to reconfigure themselves into an expanded configuration, as shown in Fig. 35B.

[0135] Moreover, as release wire **156** is tensioned, the terminal looped end **310** of suture **132**, which is threaded at least partially through the looped distal end of release wire **156**, may be pulled proximally further into pusher coil body **296**, as shown in Fig. 35C, to force the distal knot or protrusion **133** against the distal anchor **82** to approximate anchor **82** towards proximal anchor **84** and locking mechanism **136**, thereby securing the plicated tissue **T** between the collapsed tissue anchors **82, 84**.

[0136] With plicated tissue **T** securely cinched between anchors **82, 84** and locking mechanism **136**, actuation member **286** may be released from second locking position **278** and urged proximally along guide track **274**, as illustrated in Fig. 36A

The proximal translation of actuation mechanism **286** and carriage **290** may pull pusher tube **294** and pusher coil body **296** proximally relative to sheath **64**. As carriage is translated through control or housing **272**, stop **300** may pass freely into and through lumen **292** while the expandable arms **306** projecting from plug body **304** may inhibit or prevent the plug from re-entering carriage **290**. Accordingly, plug body **304** may be forced to slide proximally along release suture or wire **156**, as shown in Fig. 36B.

[0137] With stop **300** freely translating within lumen **292**, the tension on release suture or wire **156** from suture element **132** and secured anchors **82**, **84** may urge the distal looped end of wire **156** out of pusher coil body **296**, thereby allowing suture element **132** to release itself from release suture or wire **156**, as illustrated in Fig. 36C. However, stop **300** may be sized with a diameter which is larger than an inner diameter of pusher coil body **296** such that stop **300** is prevented from passing distally into pusher coil body **296**. This feature may be utilized to limit the withdrawal of release suture or wire **156** and prevent it from being pulled entirely out of pusher coil body **296** when the anchors are released. Once suture element **132** has been released, needle deployment assembly **270** may be removed from the tissue manipulation assembly **14** or other instrument or from the patient body and another needle deployment assembly **270** may be reinserted to secure another region of tissue.

[0138] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Moreover, although specific configurations and applications may be shown, it is intended that the various features may be utilized in various combinations and in various types of procedures as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

CLAIMS

What is claimed is:

1. An anchor deployment assembly comprising:

at least one tissue anchor having a length of suture depending therefrom; and

an elongate member configured for advancement within a body lumen,

wherein the elongate member is configured to deploy the at least one tissue anchor, and

wherein the elongate member is further configured to disengage the suture at a location proximal to the at least one tissue anchor upon deployment of the at least one tissue anchor.

2. The anchor deployment assembly of claim 1, wherein the elongate member is configured to sever the suture at the proximal location upon deployment of the at least one tissue anchor.

3. The anchor deployment assembly of claim 2, wherein the elongate member comprises a needle assembly having a piercing tip, the piercing tip configured to sever the suture.

4. The anchor deployment assembly of claim 3, wherein the needle assembly defines at least one cut-out having sharpened edges for severing the suture.

5. The anchor deployment assembly of claim 1 further comprising a tissue grasping tool adapted to be advanced endoluminally into a body lumen, wherein the anchor deployment assembly is configured for advancement through the tissue grasping tool.

6. The anchor deployment assembly of claim 5, wherein the tissue grasping tool further comprises a first jaw member, a second jaw member pivotably coupled along the first jaw member, and a launch tube member adapted to urge the first and second jaw members between a low-profile delivery configuration and an expanded grasping configuration.

7. The anchor deployment assembly of claim 6, wherein the anchor deployment assembly is configured for advancement through the launch tube member.

8. The anchor deployment assembly of claim 6 wherein a distal end of the launch tube member is pivotably coupled to the second jaw member.

9. The anchor deployment assembly of claim 5 further comprising a tissue engagement device having a distal end effector adapted to reversibly engage tissue and further adapted to be positioned endoluminally within the body lumen adjacent to the tissue grasping tool.

10. The anchor deployment assembly of claim 9 wherein the distal end effector comprises a helical member having a tissue piercing tip.

11. The anchor deployment assembly of claim 9 wherein the distal end effector comprises a grasper for reversibly engaging the tissue.

12. The anchor deployment assembly of claim 1 further comprising an endoscopic device having a flexible body, the flexible body adapted to be rigidized to maintain an arbitrary shape, wherein the anchor deployment assembly is configured for advancement through the endoscopic device.

13. The anchor deployment assembly of claim 12, wherein the endoscopic device comprises a steerable distal section.

14. A method of securing tissue within a hollow body organ, comprising:

advancing a needle of an anchor deployment assembly through engaged tissue;

deploying a distal tissue anchor through the needle on a distal side of the engaged tissue;

retracting the needle to a proximal side of the engaged tissue;

deploying a proximal tissue anchor through the needle on the proximal side of the engaged tissue; and

severing a suture element connecting the proximal and distal tissue anchors with the needle proximal of the proximal anchor, thereby releasing the proximal and distal anchors from the anchor deployment assembly.

15. The method of claim 14 further comprising cinching the proximal and distal anchors to secure the engaged tissue prior to severing the suture element.

16. The method of claim 14, wherein severing the suture element with the needle further comprises severing the suture element via sharpened cut-outs defined in the needle.

17. The method of claim 14 wherein deploying the proximal and distal anchors through the needle further comprises advancing a pusher through the needle.

18. The method of claim 14 further comprising, prior to advancing the needle through the engaged tissue, endoluminally advancing a tissue grasping tool pivotably coupled to a distal end of an elongate member into the hollow body organ;

reversibly engaging the tissue within the hollow body organ with a distal end effector positioned adjacently to the tissue grasping tool; and

clamping the engaged tissue with the tissue grasping tool.

19. The method of claim 18 wherein endoluminally advancing comprises advancing the tissue grasping tool transesophageally into a stomach.

20. The method of claim 18 further comprising, prior to advancing the needle through the engaged tissue, positioning the anchor deployment assembly at least partially within the tissue grasping tool.

21. A method of securing tissue within a hollow body organ, comprising:

deploying a tissue anchor assembly through a needle of an anchor deployment assembly, thereby securing engaged tissue; and

severing a suture element attached to the tissue anchor assembly with the needle proximal of the proximal anchor, thereby releasing the tissue anchor assembly from the anchor deployment assembly.

22. A tissue anchor deployment system, comprising:

a tissue grasping tool pivotably coupled to a distal end of an elongate member and adapted to be advanced endoluminally into a body lumen; and

at least one cutting element disposed upon the tissue grasping tool, wherein the at least one cutting element is adapted to sever a length of suture depending from the tissue grasping tool.

23. The system of claim 22 further comprising a tissue engagement device having a distal end effector adapted to reversibly engage tissue and further adapted to be positioned endoluminally within the body lumen adjacent to the tissue grasping tool.

24. The system of claim 22 wherein the tissue grasping tool comprises a first jaw member pivotably coupled to the distal end of the elongate member, a second jaw member pivotably coupled along the first jaw member, and a launch tube member adapted to urge the first and second jaw members between a low-profile delivery configuration and an expanded grasping configuration.

25. The system of claim 24 wherein the at least one cutting element comprises a blade having a cutting edge.

26. The system of claim 24 wherein the at least one cutting element is positioned along the first jaw, the second jaw, or both the first and second jaws.

27. The system of claim 24 wherein the at least one cutting element is adapted to sever the length of suture depending from the launch tube member.

28. A method of deploying tissue anchors within a hollow body organ, comprising:

endoluminally advancing a tissue grasping tool pivotably coupled to a distal end of an elongate member into the hollow body organ;

clamping tissue within the hollow body organ with the tissue grasping tool;

deploying at least one tissue anchor into or through the tissue via the tissue grasping tool; and

severing a length of suture connecting the deployed at least one tissue anchor and depending from the tissue grasping tool with at least one cutting element disposed upon the tissue grasping tool.

29. The method of claim 28 wherein endoluminally advancing comprises advancing the tissue grasping tool transesophageally into a stomach.

30. The method of claim 28 wherein endoluminally advancing comprises advancing the tissue grasping tool along a flexible body with a steerable distal section transesophageally, wherein the flexible body is adapted to be rigidized to maintain an arbitrary shape.

31. An anchor deployment assembly comprising:

an elongate member adapted for advancement within a body lumen and being further adapted to deploy at least one tissue anchor having a length of suture depending therefrom,

wherein the elongate member comprises a suture cutting element disposed thereon which is adapted to sever a portion of the suture via thermal energy.

32. The anchor deployment assembly of claim 31 wherein the elongate member is configured to sever the portion of suture upon deployment of the at least one tissue anchor.

33. The anchor deployment assembly of claim 32 wherein the elongate member comprises a tubular member advanceable through a needle assembly having a piercing tip.

34. The anchor deployment assembly of claim 31 wherein the suture cutting element is disposed on a distal end of the elongate member.

35. The anchor deployment assembly of claim 31 wherein the suture cutting element is integrally disposed along the elongate member.

36. The anchor deployment assembly of claim 31 wherein the assembly is configured to insulate the suture cutting element from surrounding tissue.

37. The anchor deployment assembly of claim 36 wherein the suture cutting element is insulated via an insulating element disposed distally of the suture cutting element.

38. The anchor deployment assembly of claim 36 wherein the suture cutting element is covered at least partially within an insulative covering.

39. The anchor deployment assembly of claim 31 further comprising a power supply in electrical communication with the suture cutting element.

40. The anchor deployment assembly of claim 39 further comprising an actuator in electrical communication with the power supply.

41. The anchor deployment assembly of claim 40 wherein the actuator comprises a foot pedal or hand switch.

42. A method of securing tissue within a hollow body organ, comprising:

endoluminally advancing an anchor deployment assembly through engaged tissue;

deploying a distal tissue anchor through a needle on a distal side of the engaged tissue;

retracting the needle to a proximal side of the engaged tissue;

deploying a proximal tissue anchor through the needle on the proximal side of the engaged tissue; and

severing a suture element connecting the proximal and distal tissue anchors via thermal energy applied via a suture cutting element to thereby releasing the proximal and distal anchors from the anchor deployment assembly.

43. The method of claim 42 wherein endoluminally advancing comprises advancing the anchor deployment assembly transesophageally into a stomach.

44. The method of claim 42 further comprising cinching the proximal and distal anchors to secure the engaged tissue prior to severing the suture element.

45. The method of claim 44 wherein cinching the proximal and distal anchors comprises advancing a pusher through the needle.

46. The method of claim 42 wherein severing a suture element comprises applying electrical energy to the suture cutting element such that the element increases in temperature to thereby sever the suture element.

47. The method of claim 46 wherein applying electrical energy comprises applying the energy cyclically.

48. The method of claim 47 wherein applying the energy cyclically comprises automatically applying the energy for a predetermined period of time.

49. A tissue anchor deployment system, comprising:

a housing having a guide defined along a length of the housing;

an elongate flexible shaft with a lumen defined therethrough and having a proximal end attached to the housing and a distal end having a piercing body attached thereto;

an elongate pusher member slidably disposed at least within the elongate shaft;

a retraction control member removably connected to the housing; and

a release wire slidably disposed within the elongate shaft and secured at a proximal end to the retraction control member.

50. The system of claim 49 wherein the guide defined along the length comprises a channel.

51. The system of claim 49 wherein the guide further defines at least a first locking position along the housing.

52. The system of claim 51 wherein the guide further defines at least a second locking position along the housing.

53. The system of claim 49 further comprising an actuation member translatable along the guide and attached to a proximal end of the elongate pusher member.

54. The system of claim 53 wherein the actuation member comprises a carriage slidably positioned within the housing, the carriage defining a lumen through which the release wire is disposed.

55. The system of claim 49 wherein the elongate flexible shaft comprises a catheter shaft.

56. The system of claim 49 wherein the piercing body comprises a needle body having a lumen defined therethrough.

57. The system of claim 49 wherein the elongate pusher member comprises a hollow tubular member having a length.

58. The system of claim 57 wherein the elongate pusher member further comprises a coiled body which is adapted to provide column support when pushed or pulled through the elongate flexible shaft.

59. The system of claim 49 further comprising a stop fixedly attached to a portion of the release wire.

60. The system of claim 59 wherein the stop has a diameter sized to inhibit movement through at least part of the elongate pusher member.

61. The system of claim 59 further comprising a plug member slidably located along the release wire proximal to the stop.

62. The system of claim 61 wherein the plug member comprises one or more expandable arms projecting radially from a plug body in an expanded configuration and over or around the stop in a low-profile configuration.

63. The system of claim 62 wherein the one or more expandable arms are positionable around the stop such that distal ends of the one or more expandable arms are constrained within a proximal end of a carriage positioned within the housing.

64. The system of claim 49 wherein the retraction control member comprises a threaded attachment for connection to the housing.

65. The system of claim 49 wherein the release wire comprises a nitinol wire.

66. The system of claim 49 wherein the release wire forms a loop through the elongate shaft.

67. The system of claim 66 wherein the release wire forms a loop through a length of the elongate pusher member.

68. The system of claim 49 further comprising a deployable tissue anchor assembly slidably positioned within a portion of the elongate shaft distally of the elongate pusher member.

69. The system of claim 68 wherein the tissue anchor assembly comprises at least a first tissue anchor and a second tissue anchor connected by a length of suture.

70. The system of claim 69 wherein a terminal end of the length of suture is passed at least partially through or around the release wire within the elongate shaft.

71. The system of claim 69 further comprising a locking mechanism slidably positioned along the length of suture between the tissue anchor assembly and the elongate pusher member.

72. The system of claim 49 further comprising a tissue grasping tool pivotably coupled to a distal end of an outer flexible shaft and adapted to be advanced endoluminally into a body lumen, wherein the elongate flexible shaft with the distal end having a piercing body is sized for advancement through the outer flexible shaft and through the tissue grasping tool.

73. The system of claim 72 wherein the tissue grasping tool comprises a first jaw member pivotably coupled to a distal end of the outer flexible shaft, a second jaw member pivotably coupled along the first jaw member, and a launch tube member adapted to urge the first and second jaw members between a low-profile delivery configuration and an expanded grasping configuration.

74. The system of claim 72 further comprising a tissue engagement device having a helical tissue engager adapted to reversibly engage tissue and further adapted to be positioned endoluminally within the body lumen adjacent to the tissue grasping tool.

75. The system of claim 72 further comprising an endoluminal elongate body adapted to transition between a flexible state and a rigid state, wherein the tissue grasping tool and the elongate flexible shaft are removably advanceable therethrough.

76. The system of claim 75 wherein the endoluminal elongate body comprises a steerable distal portion.

77. A method of securing tissue within a hollow body organ, comprising:

endoluminally advancing through engaged tissue an elongate flexible shaft having a proximal end attached to a housing and a distal end having a piercing body attached thereto;

actuating an actuation member on the housing to urge an elongate pusher member distally through the elongate flexible shaft such that a first tissue anchor is urged from the piercing body into or against a first side of the engaged tissue;

retracting the elongate flexible shaft to a second side of the engaged tissue;

further actuating the actuation member on the housing to urge the elongate pusher member further distally through the elongate flexible shaft such that a second

tissue anchor is urged from the piercing body into or against a second side of the engaged tissue;

tensioning a release wire proximally through the elongate flexible shaft such that a suture element connecting the first and second tissue anchors is tensioned and a stop attached to a portion of the release wire is freed from a plug member located along the release wire proximally of the stop;

retracting the elongate pusher member relative to the elongate flexible shaft such that a distal looped portion of the release wire is exposed to release a terminal end of the suture element.

78. The method of claim 77 wherein endoluminally advancing comprises advancing the elongate flexible shaft trans-esophageally into a stomach.

79. The method of claim 77 wherein actuating an actuation member comprises distally advancing a slide mechanism along the housing to urge the elongate pusher member relative to the elongate flexible shaft.

80. The method of claim 79 further comprising unlocking the actuation member from a first locking position along the housing prior to actuating an actuation member.

81. The method of claim 79 further comprising locking the actuation member into a second locking position along the housing prior to tensioning a release wire.

82. The method of claim 77 wherein further actuating comprises distally advancing a slide mechanism along the housing to a distal position to urge the elongate pusher member relative to the elongate flexible shaft.

83. The method of claim 77 wherein tensioning comprises pulling the release wire proximally through the elongate flexible shaft and housing.

84. The method of claim 77 wherein tensioning comprises approximating the first and second tissue anchors towards one another to secure the engaged tissue therebetween.

85. The method of claim 77 wherein tensioning further comprises uni-directionally advancing a locking mechanism along the suture element proximal to the first and second tissue anchors.

86. The method of claim 77 wherein retracting comprises distally passing the stop at least partially into the elongate pusher member to expose the distal looped portion of the release wire.

87. The method of claim 77 further comprising grasping the tissue within the hollow body organ with a tissue grasping instrument prior to actuating an actuation member.

88. The method of claim 87 wherein endoluminally advancing comprises advancing the elongate flexible shaft through the tissue grasping instrument.

89. The method of claim 88 further comprising advancing the tissue grasping instrument along or through a flexible body with a steerable distal section, wherein the flexible body is adapted to be rigidized to maintain an arbitrary shape.

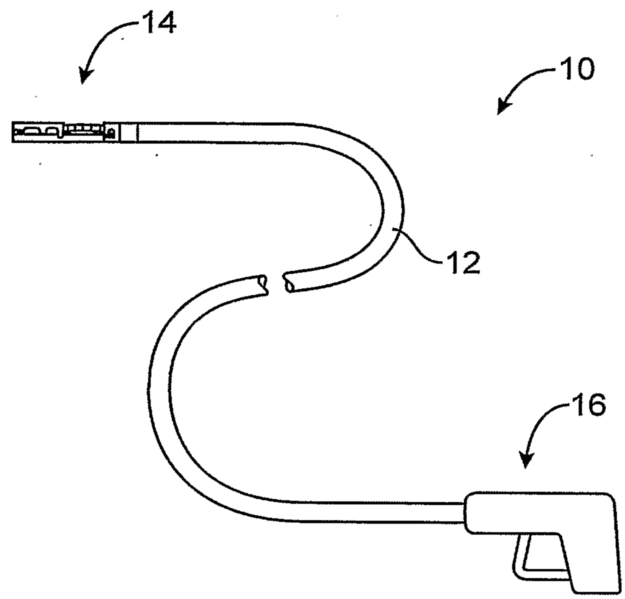

FIG. 1A

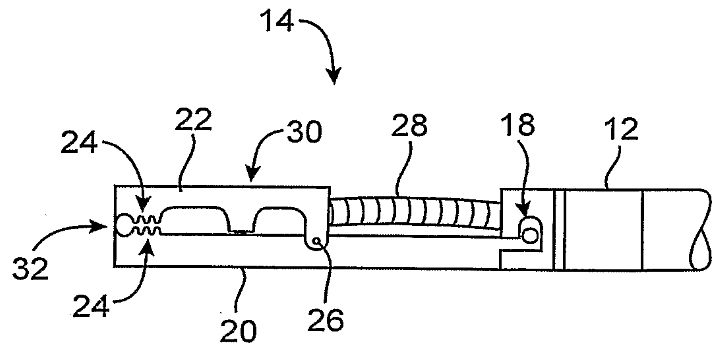

FIG. 1B

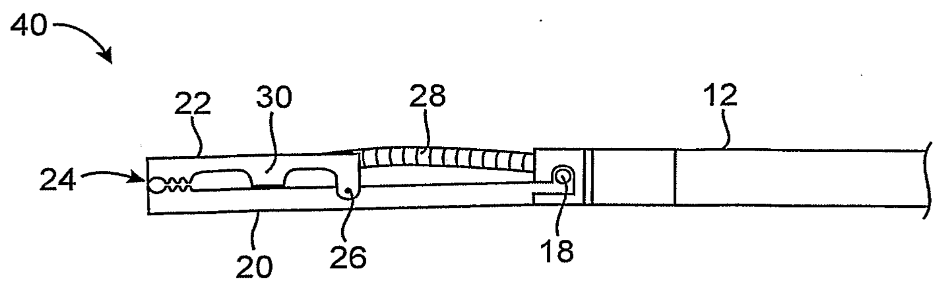

FIG. 2A

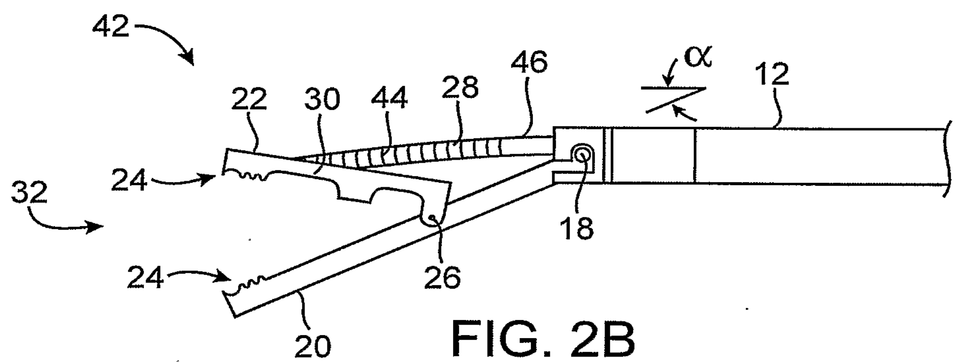

FIG. 2B

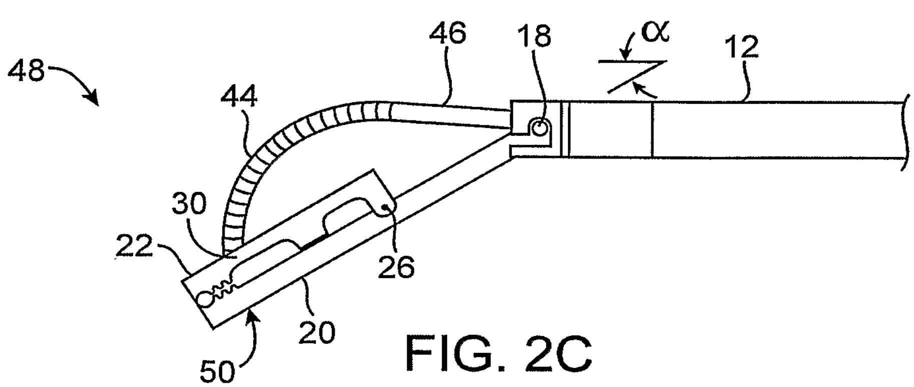

FIG. 2C

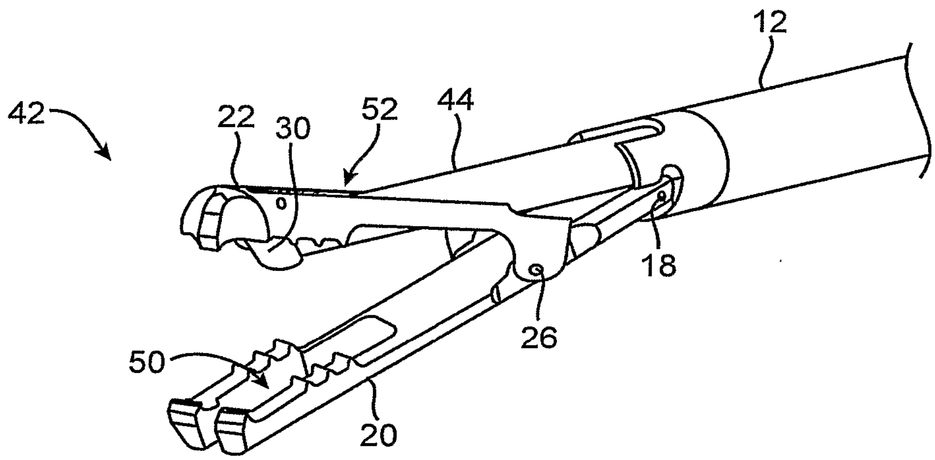

FIG. 3A

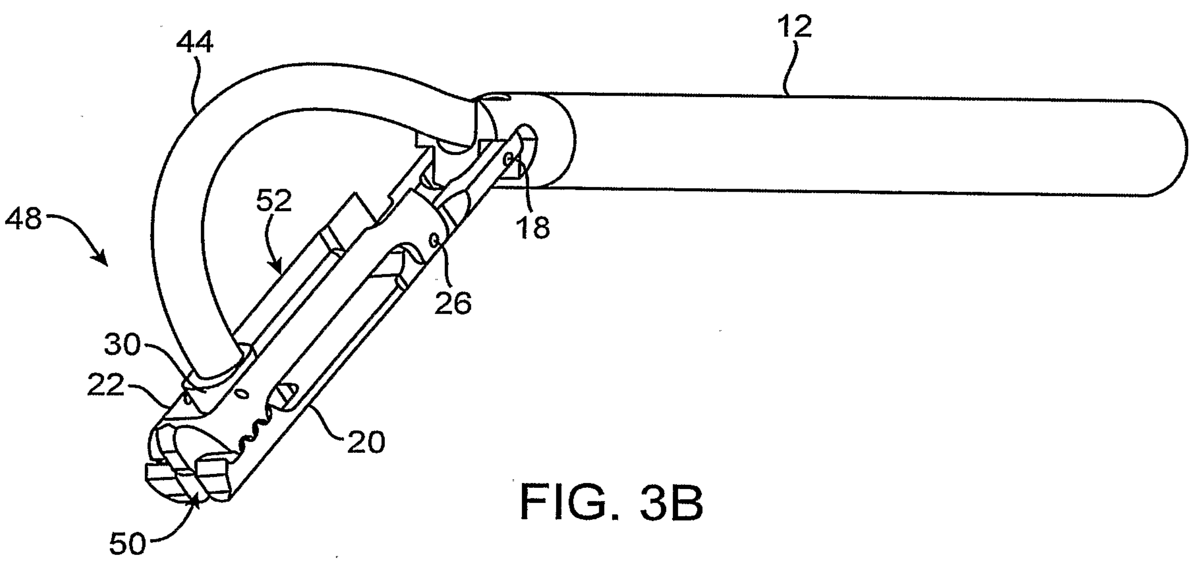

FIG. 3B

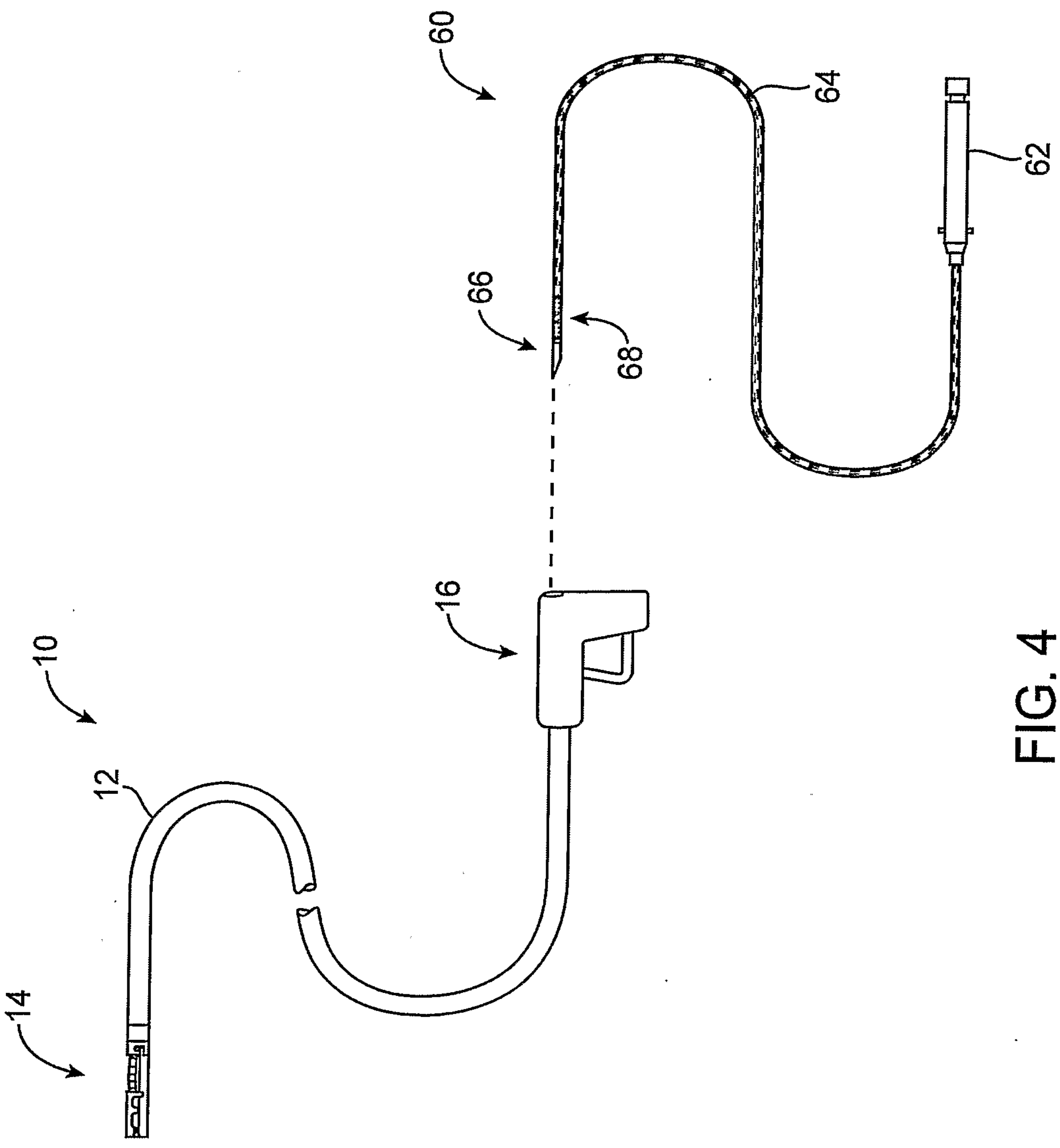

FIG. 4

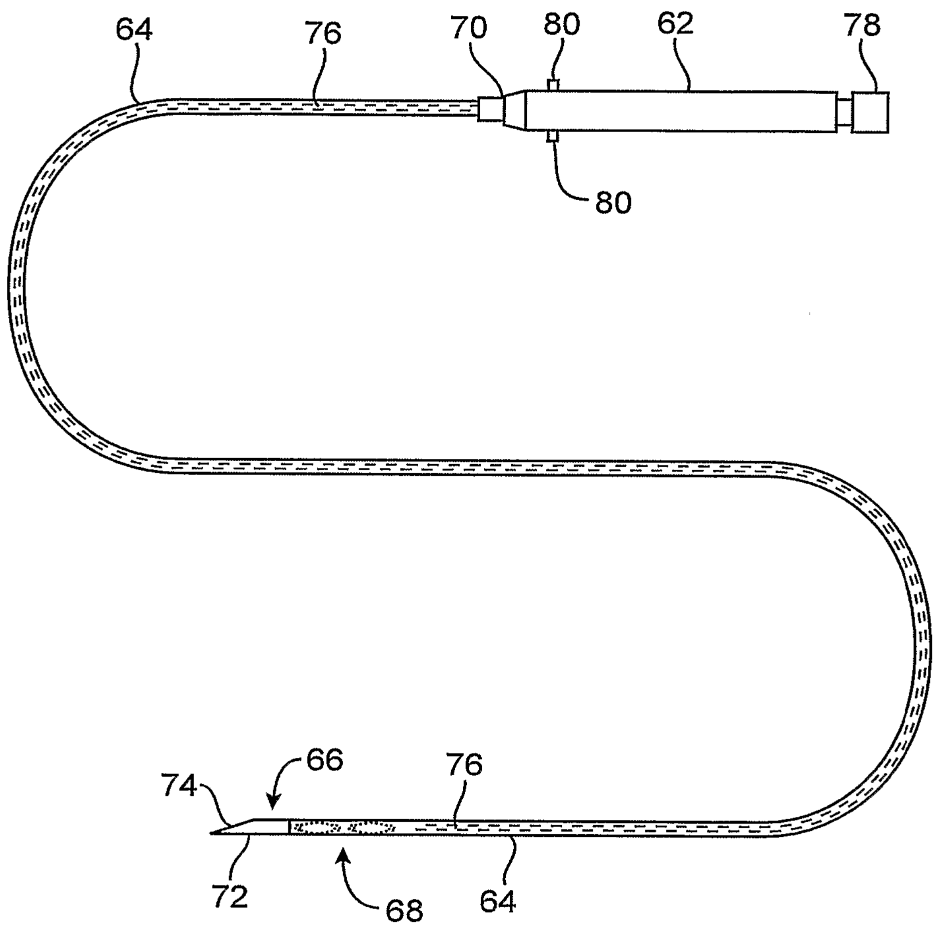

FIG. 5A

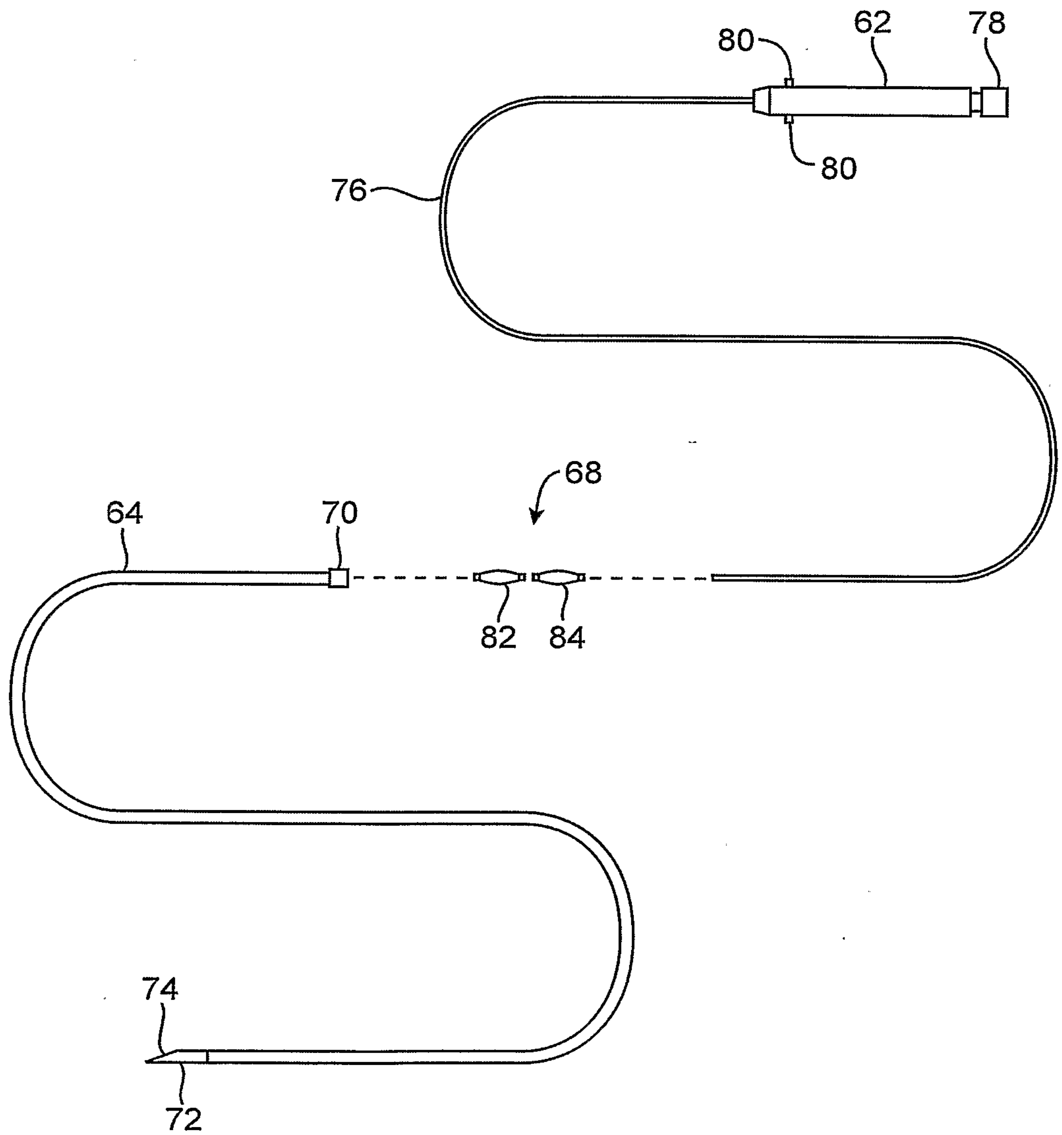

FIG. 5B

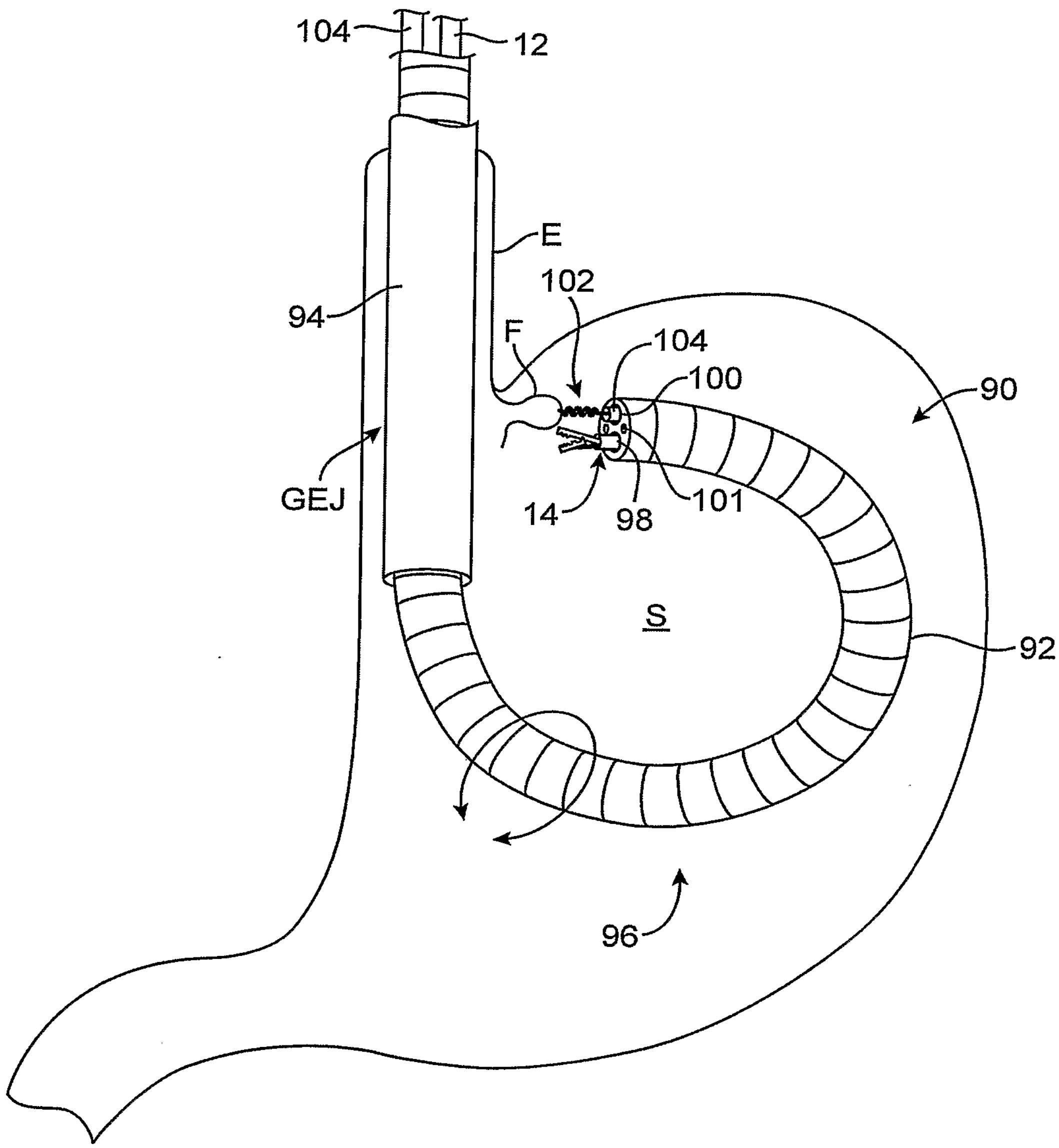

FIG. 6

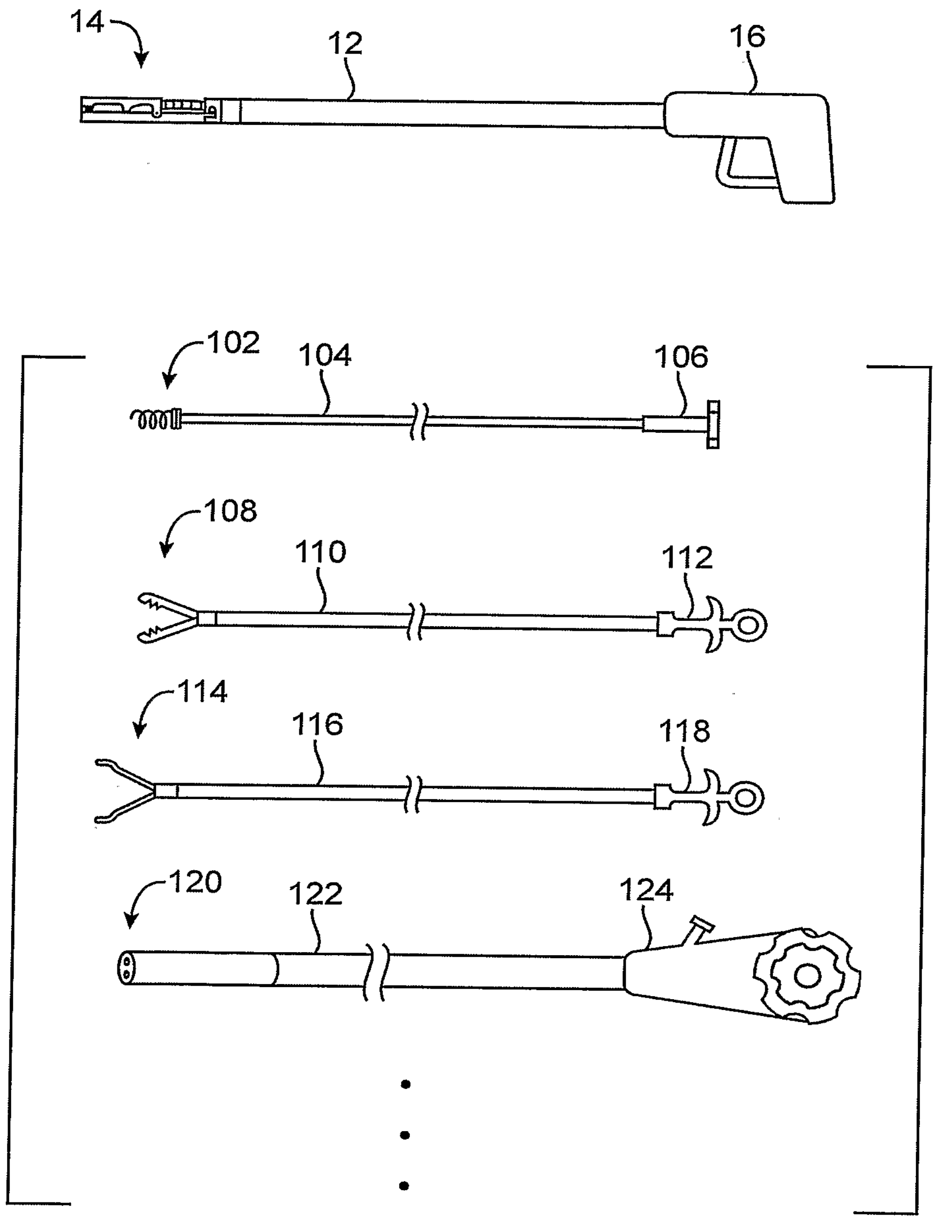

FIG. 7

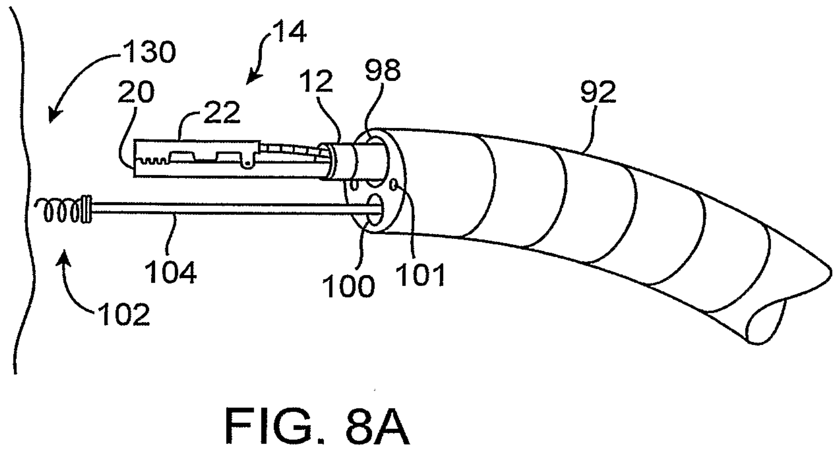

FIG. 8A

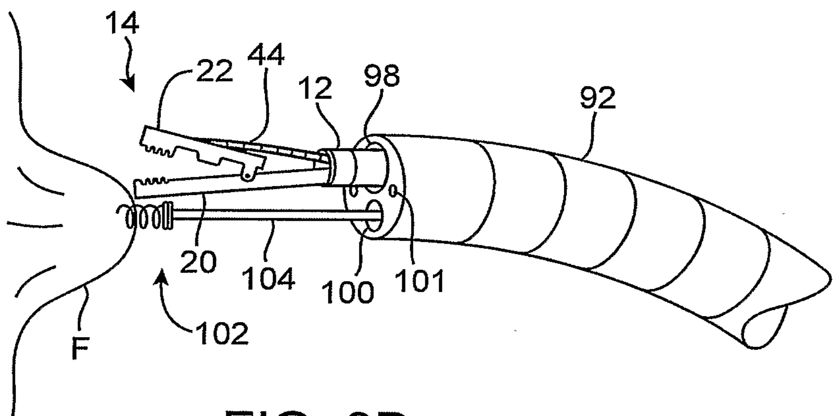

FIG. 8B

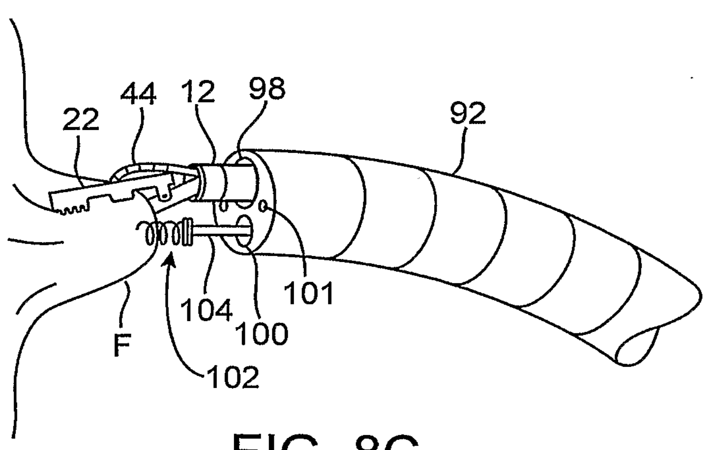

FIG. 8C

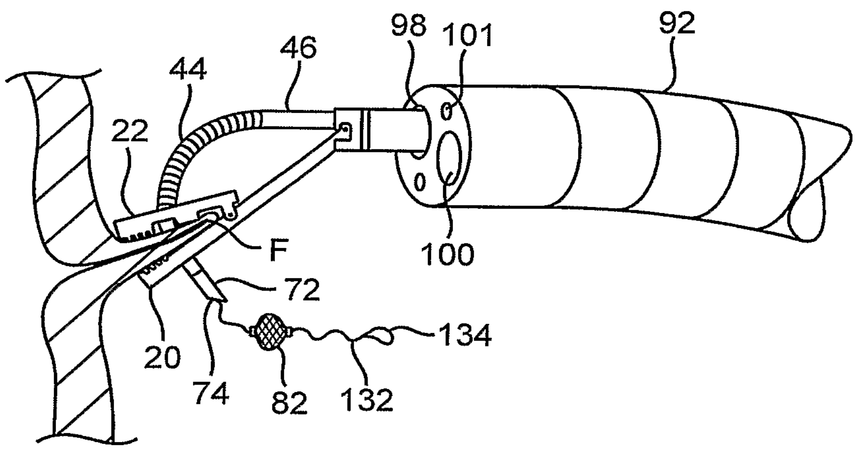

FIG. 8D

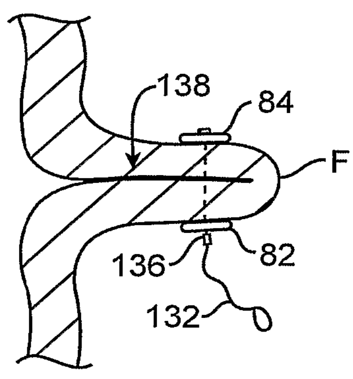

FIG. 9A

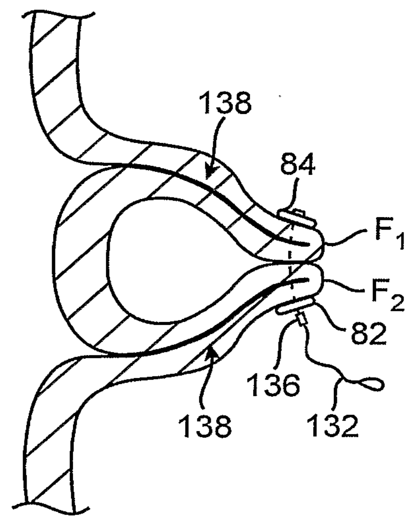

FIG. 9B

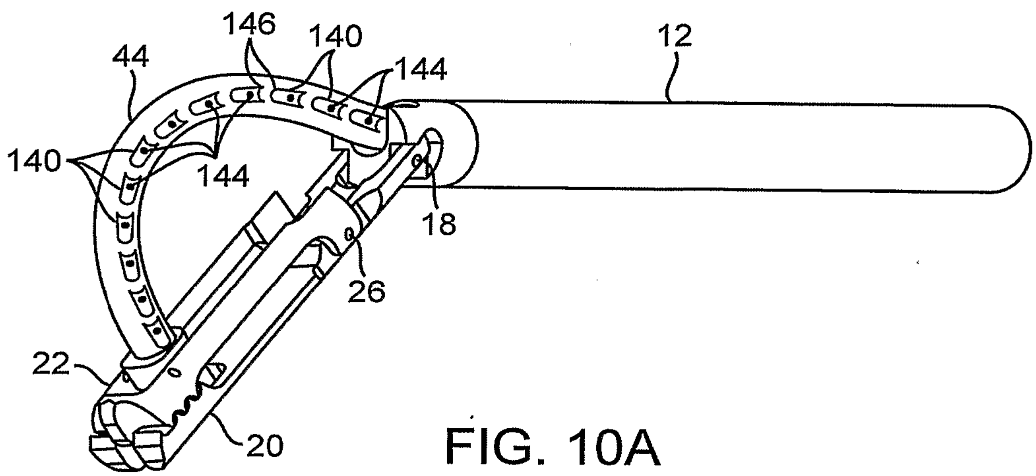

FIG. 10A

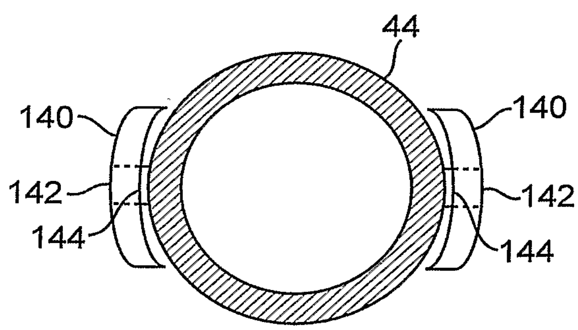

FIG. 10B

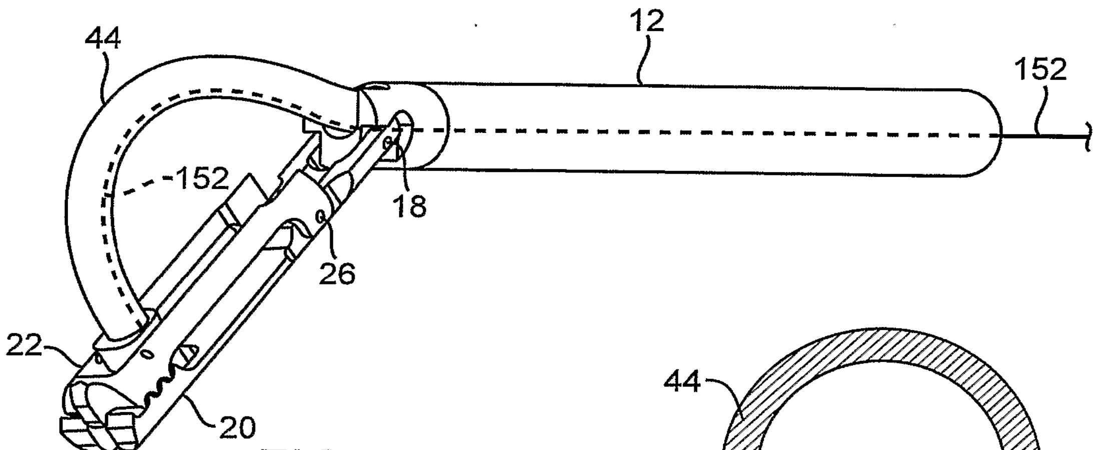

FIG. 11A

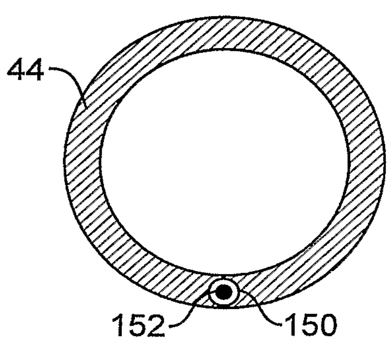

FIG. 11B

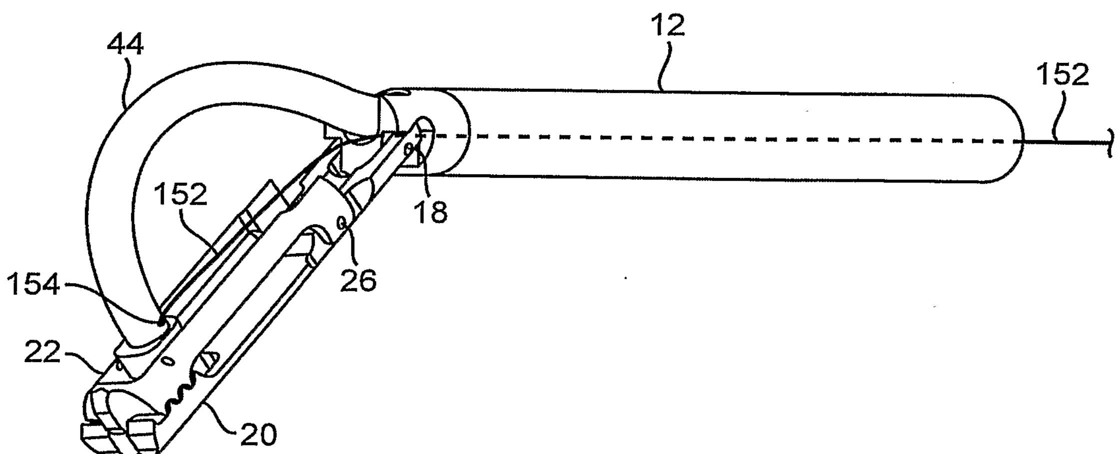

FIG. 12

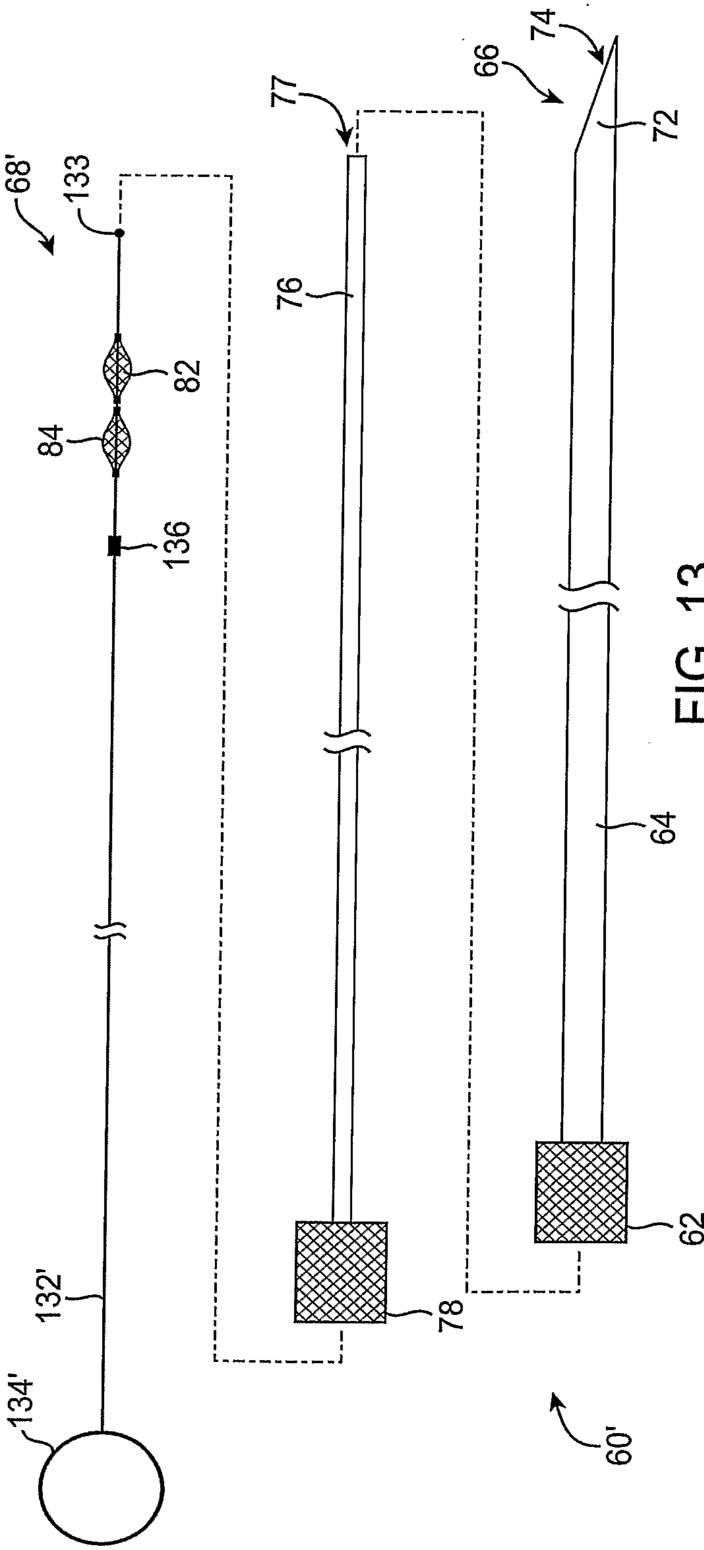
68'
133
82
84
136
132'
134'
77
76
78
66
74
72
64
62
60'

FIG. 13

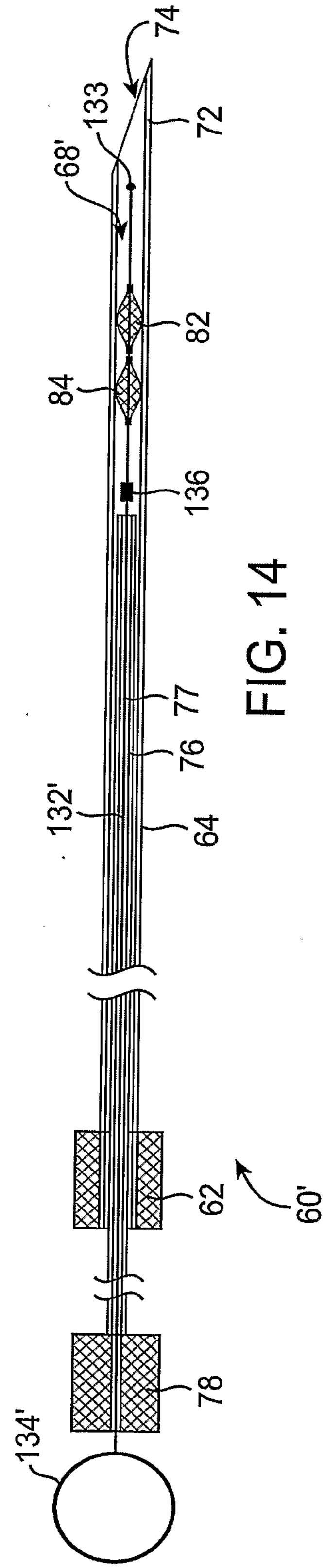
74
133
68'
72
82
84
136
77
76
132'
64
62
60'
78
134'

FIG. 14

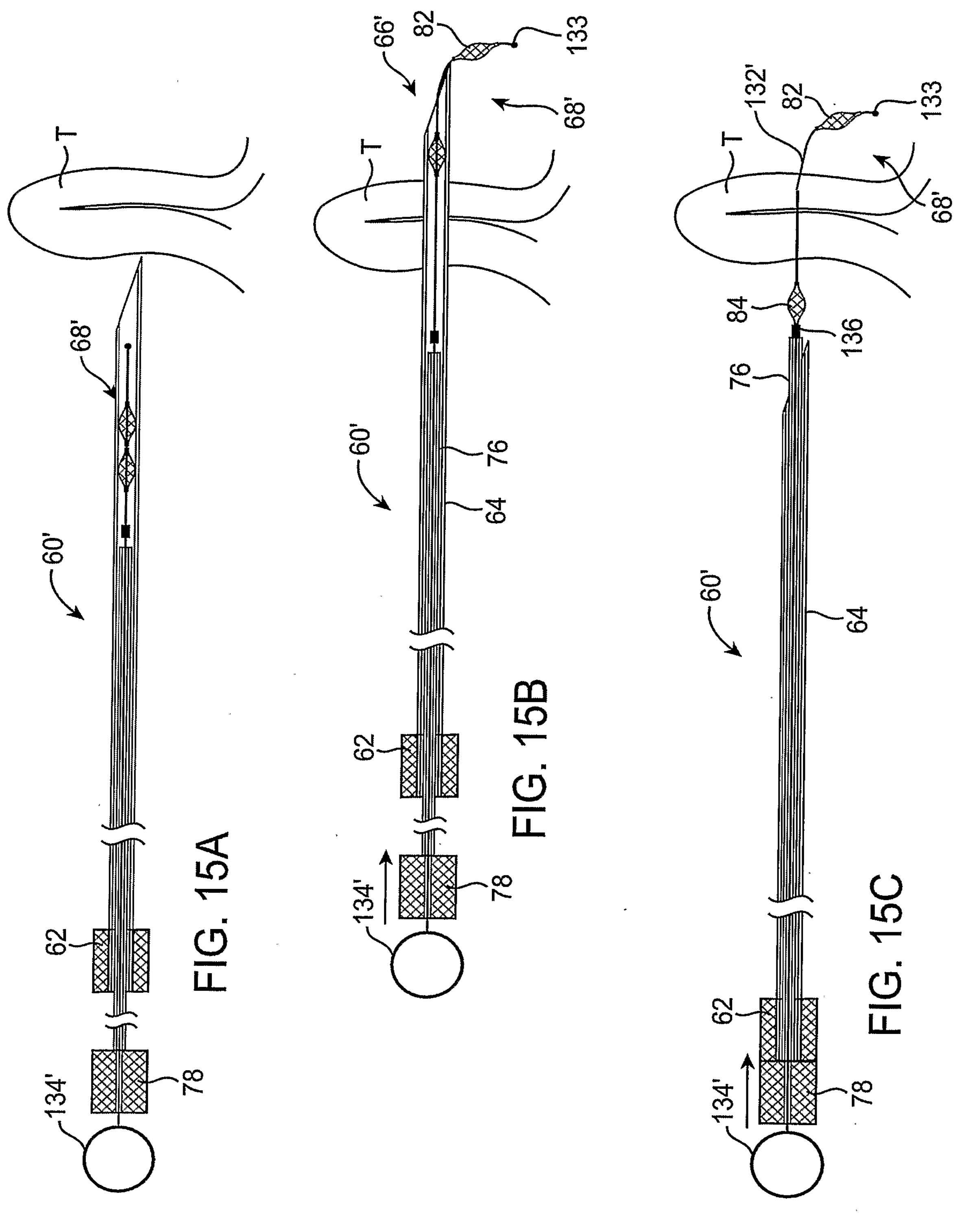

FIG. 15A

FIG. 15B

FIG. 15C

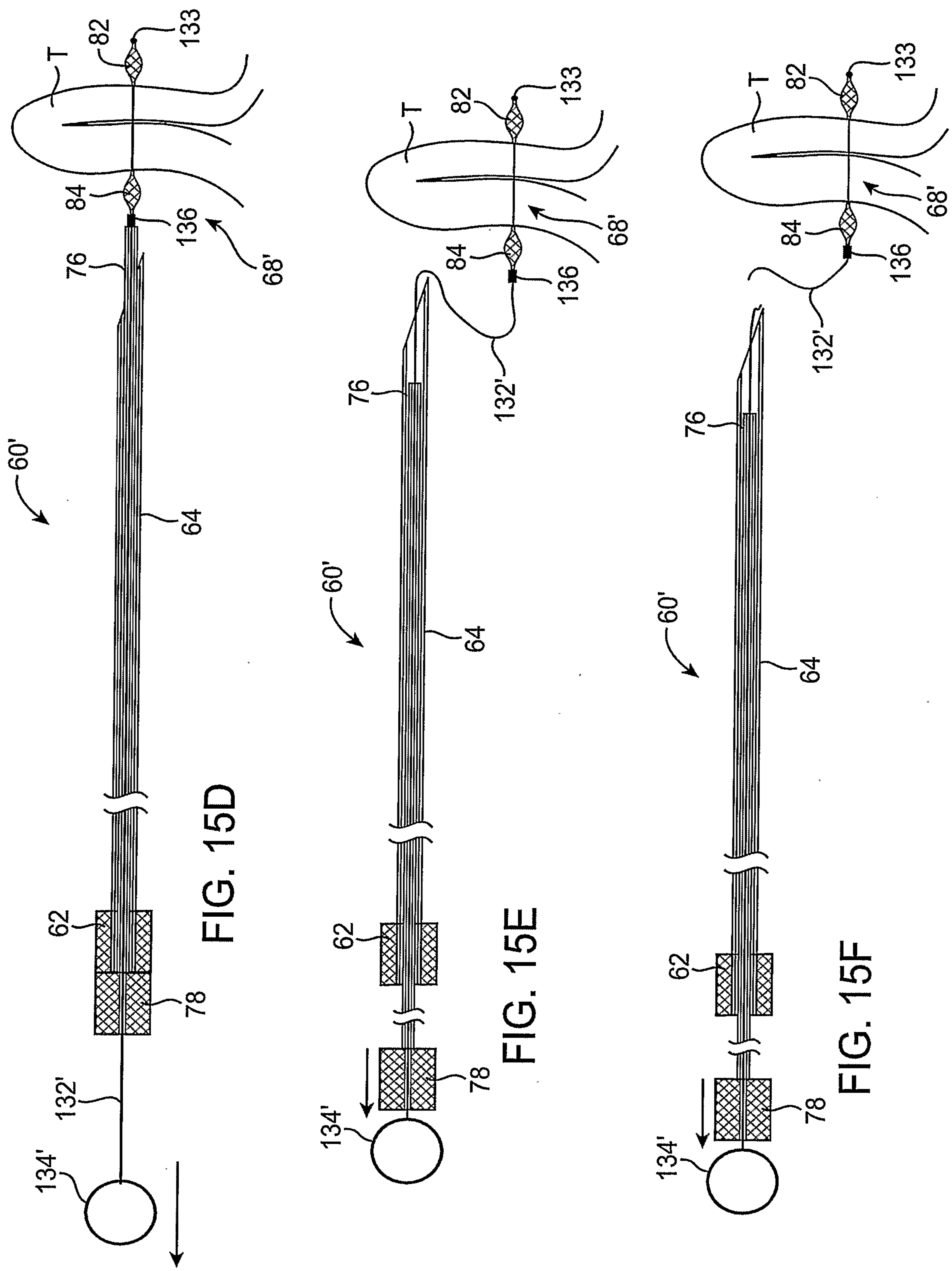

FIG. 15D

FIG. 15E

FIG. 15F

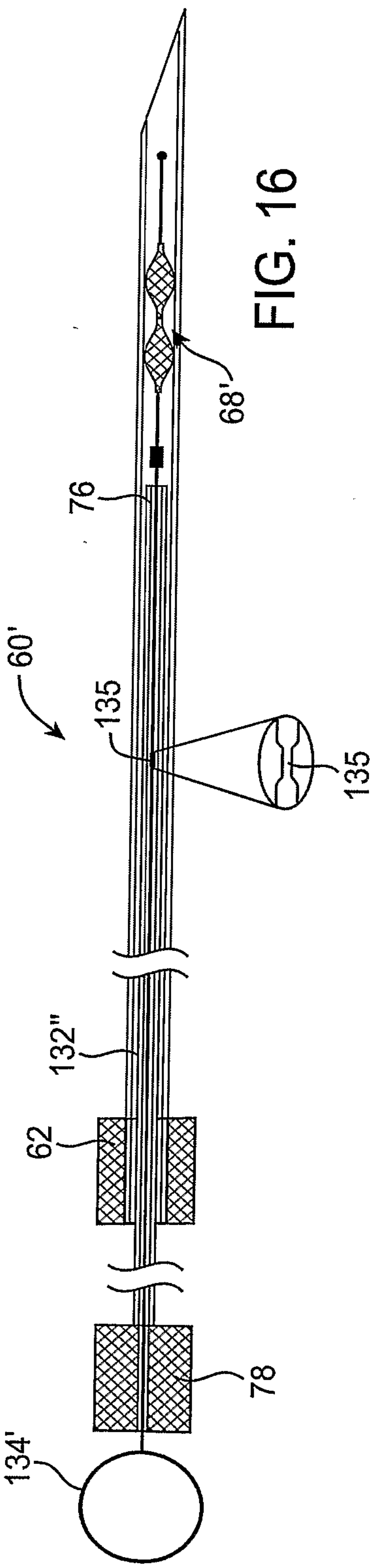

FIG. 16

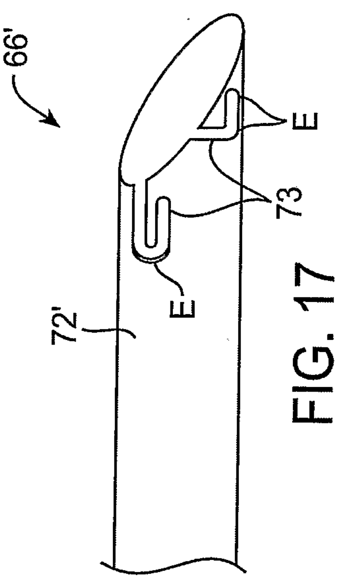

FIG. 17

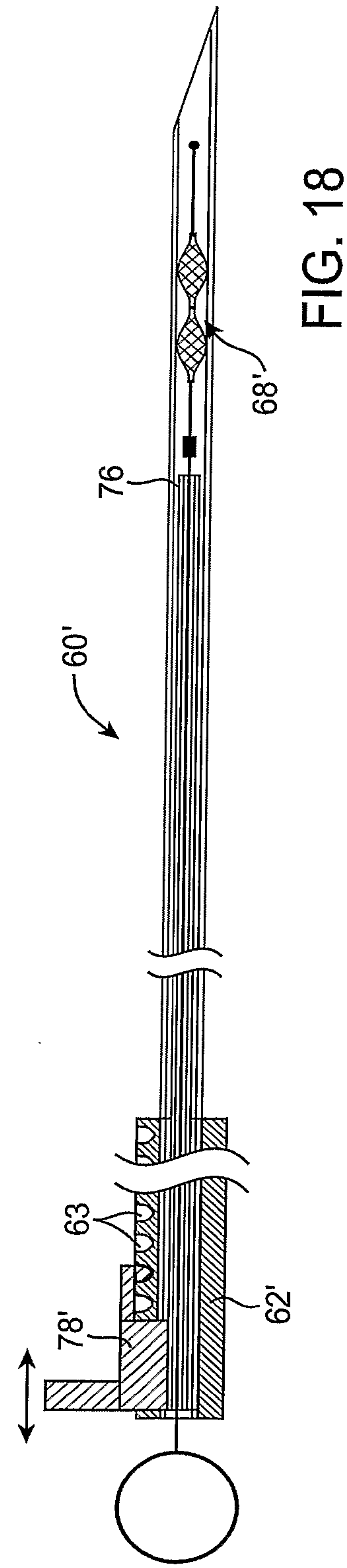

FIG. 18

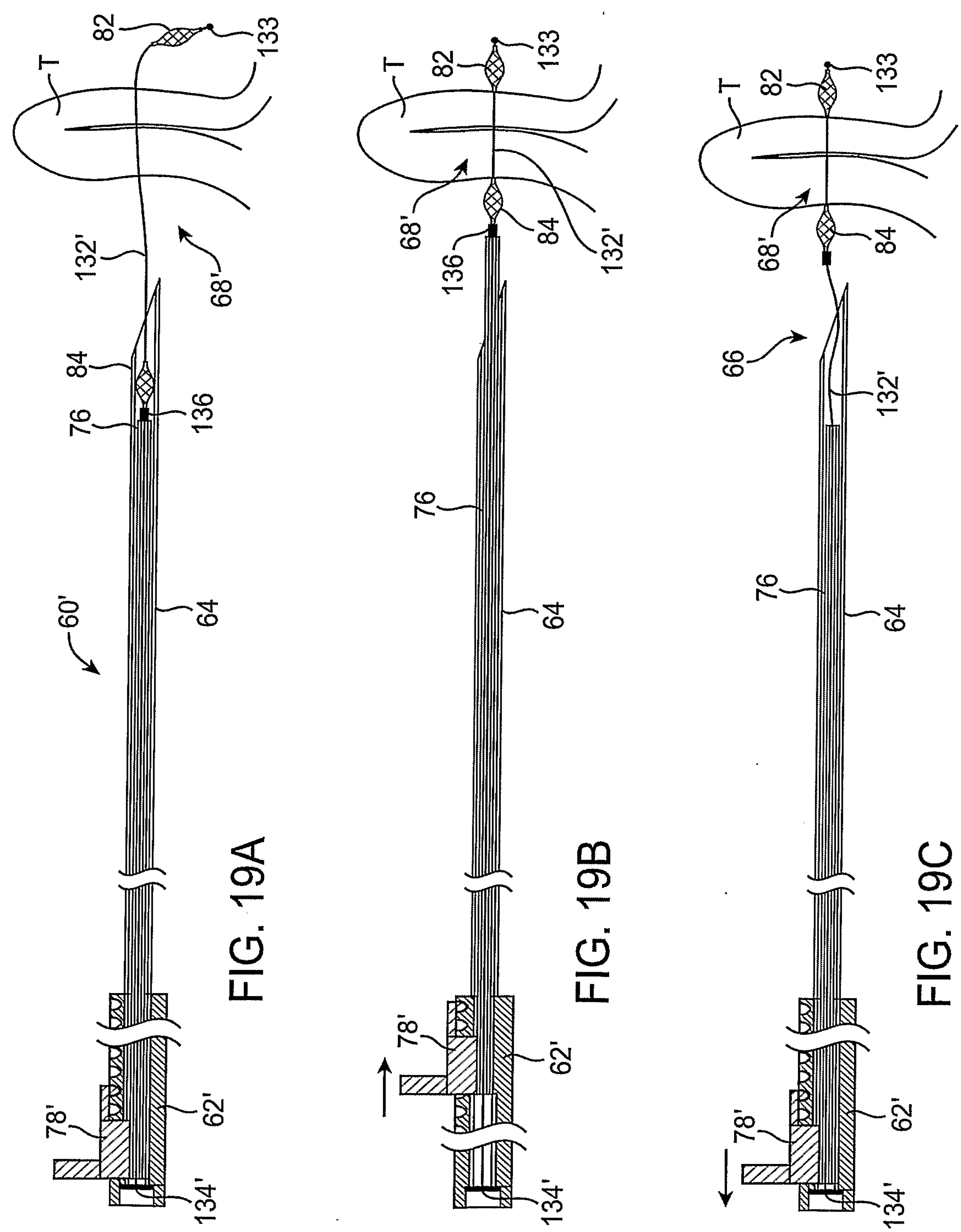

FIG. 19A

FIG. 19B

FIG. 19C

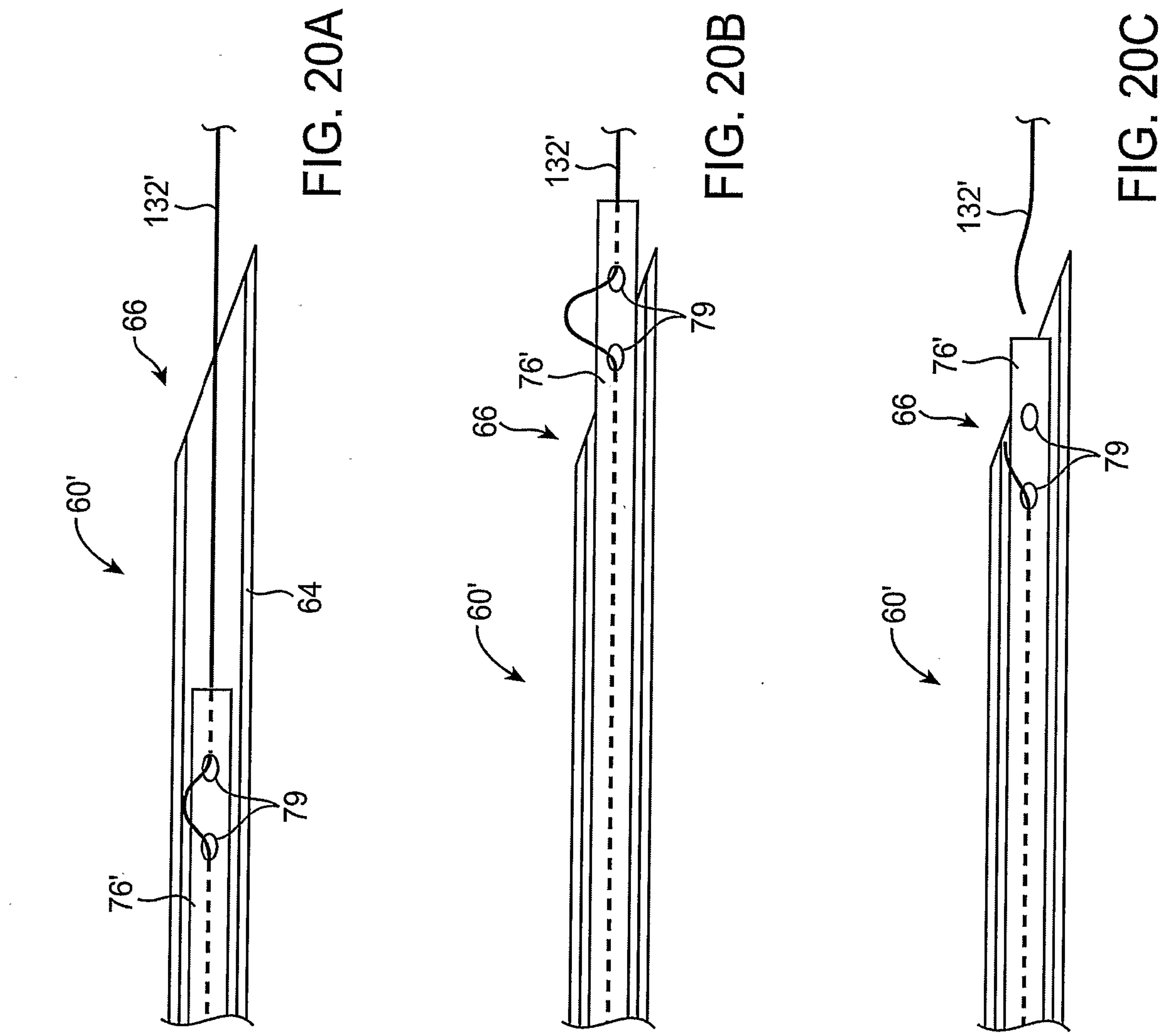

FIG. 20A

FIG. 20B

FIG. 20C

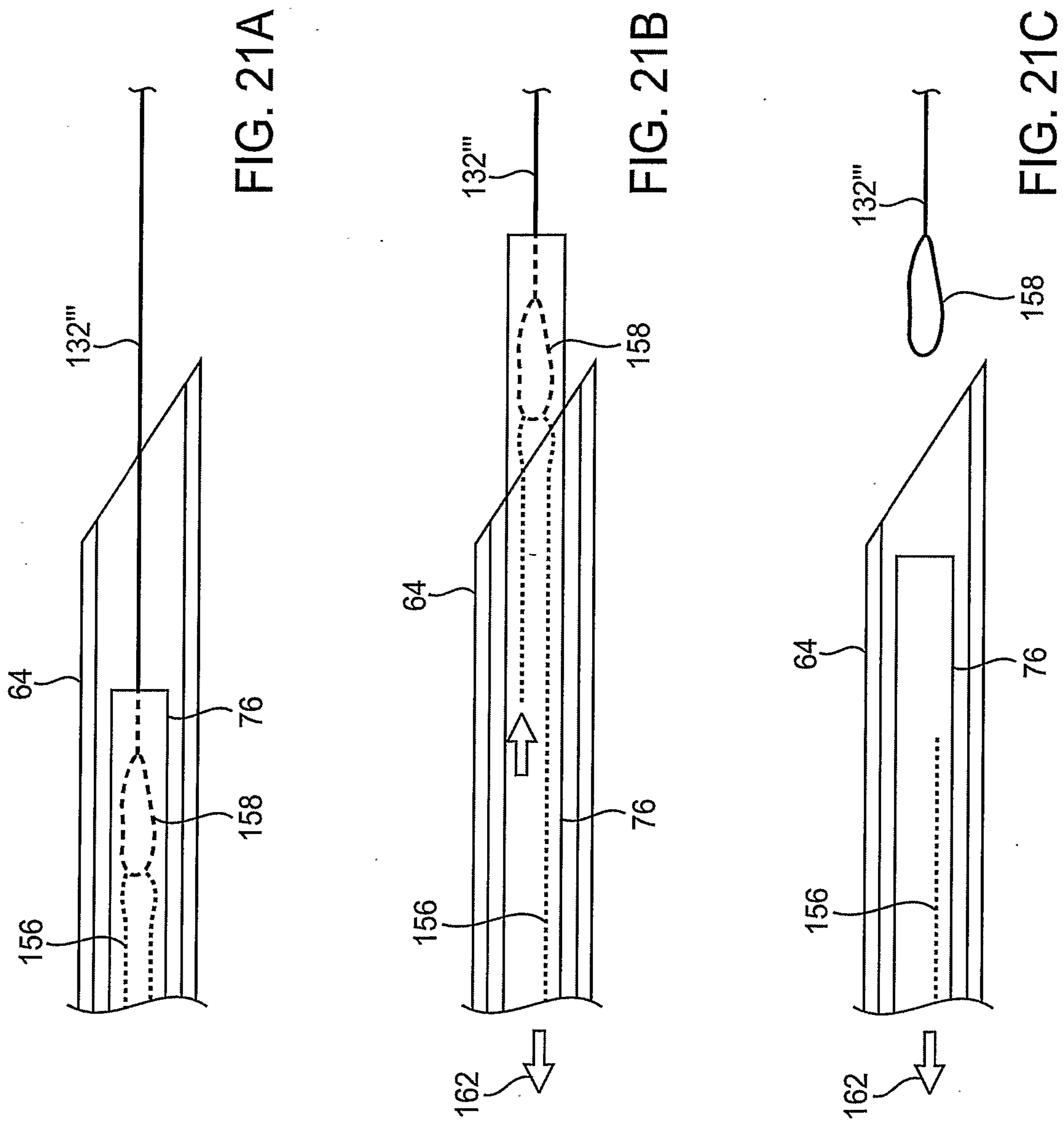

FIG. 21A

FIG. 21B

FIG. 21C

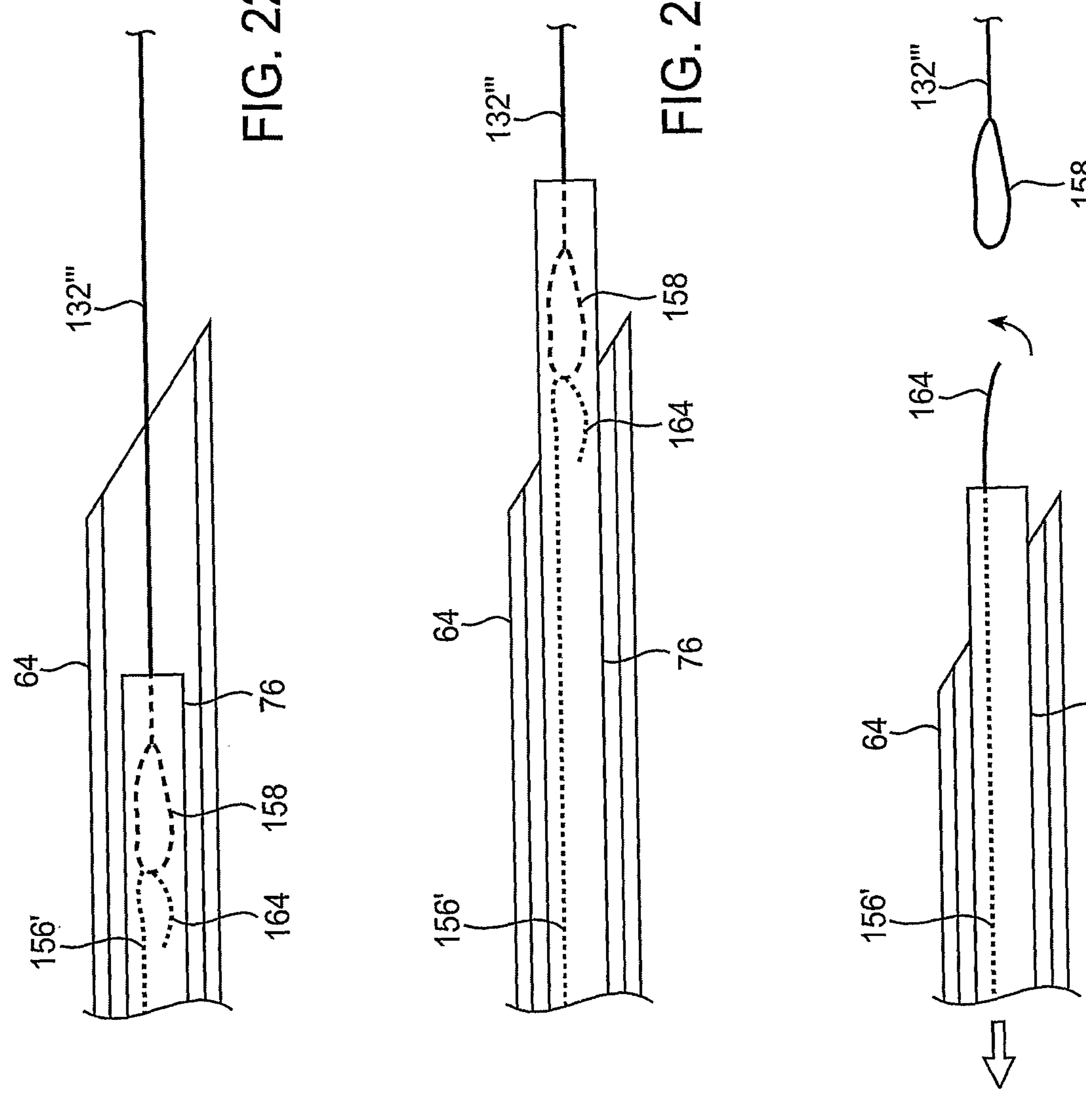

FIG. 22A

FIG. 22B

FIG. 22C

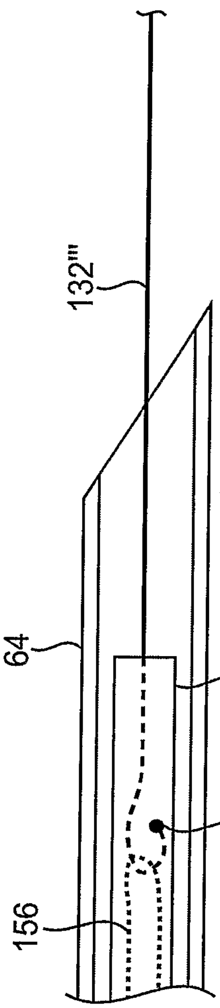

FIG. 23A

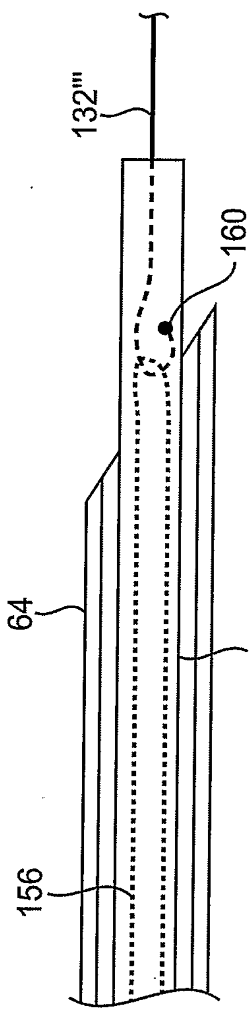

FIG. 23B

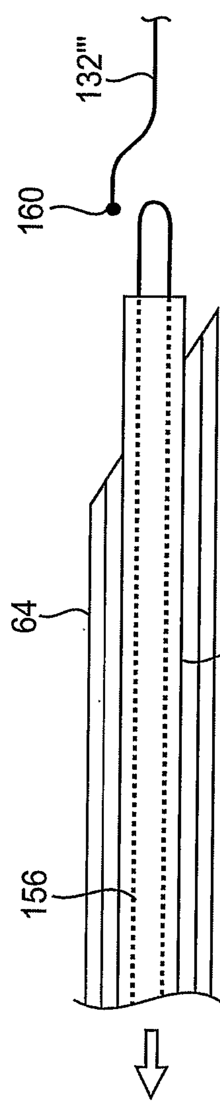

FIG. 23C

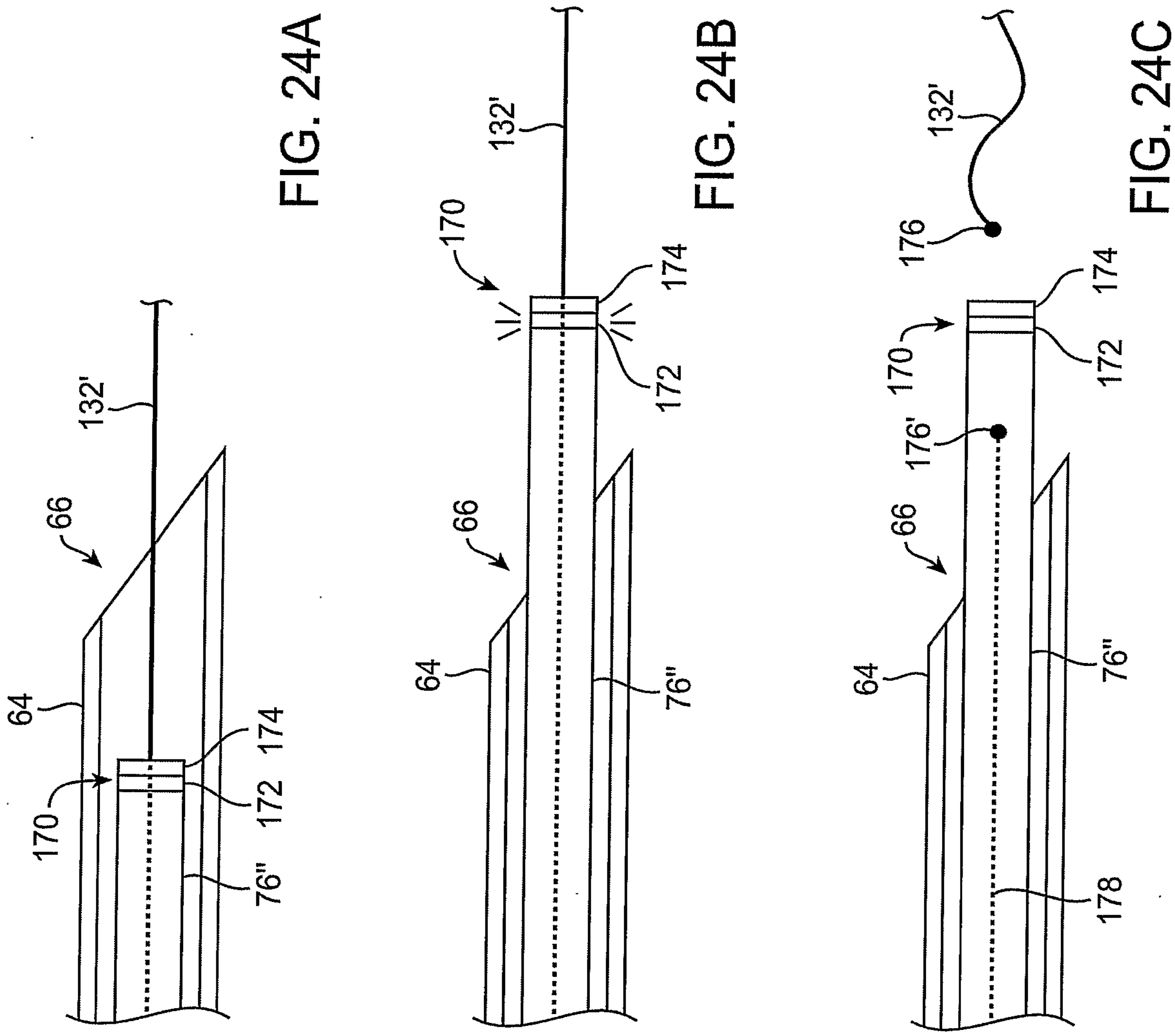

FIG. 24A

FIG. 24B

FIG. 24C

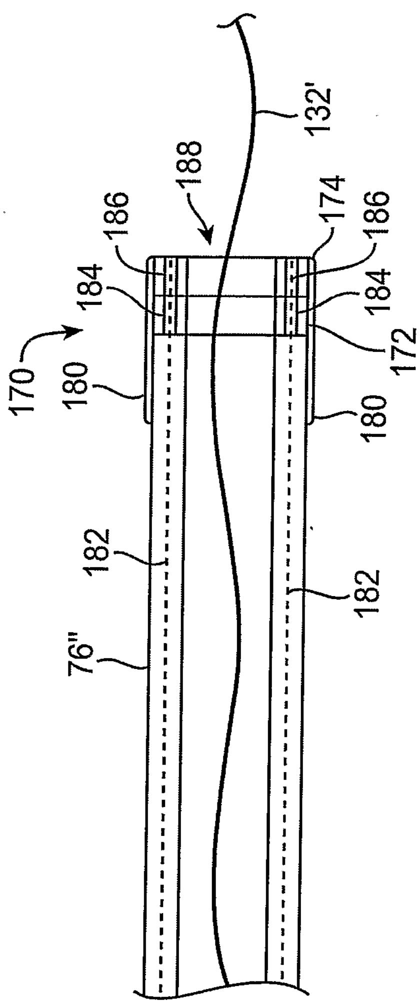

FIG. 25A

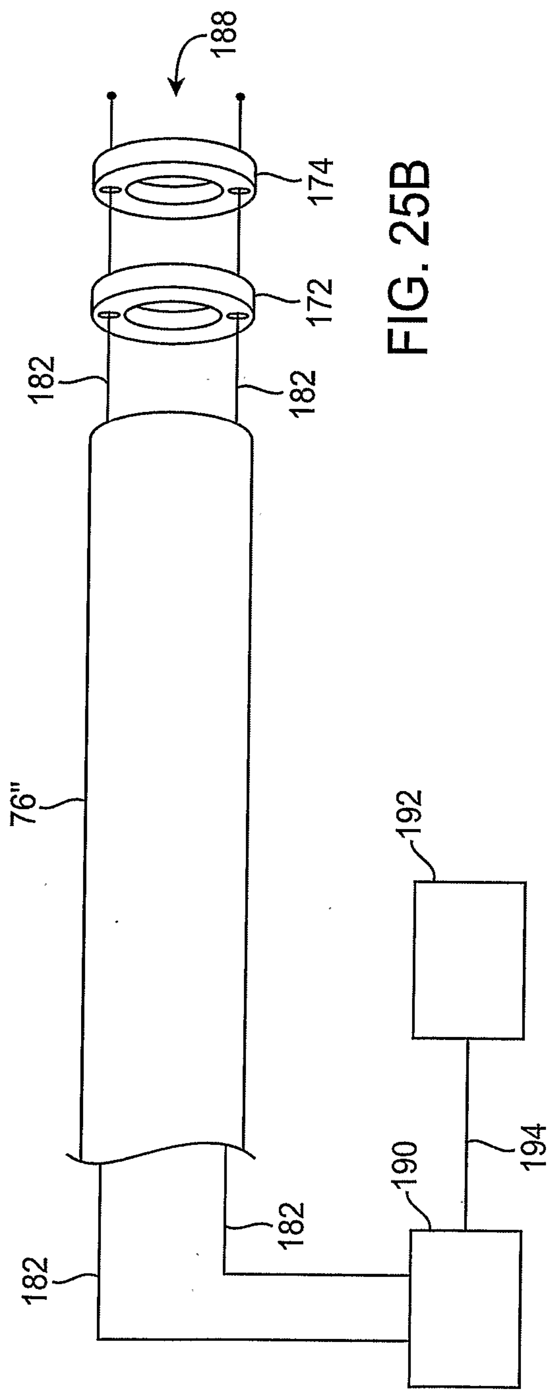

FIG. 25B

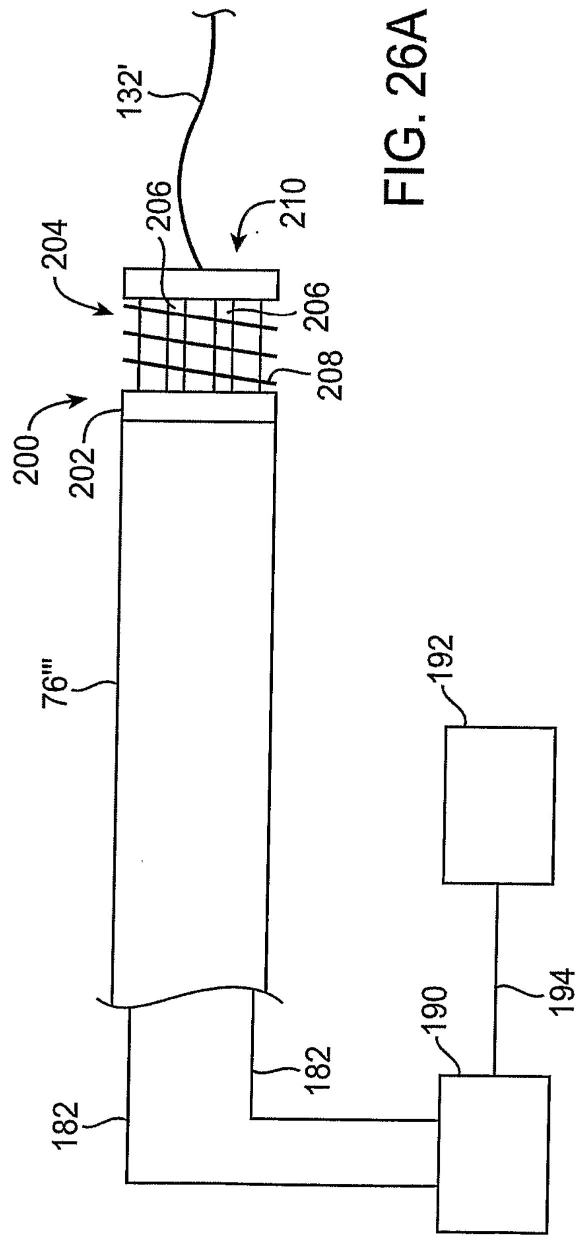

FIG. 26A

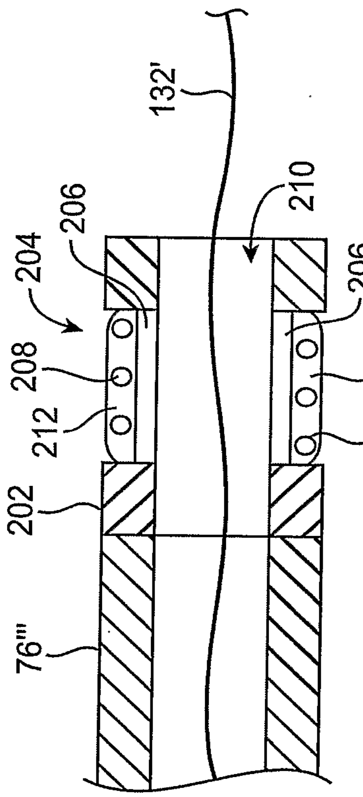

FIG. 26B

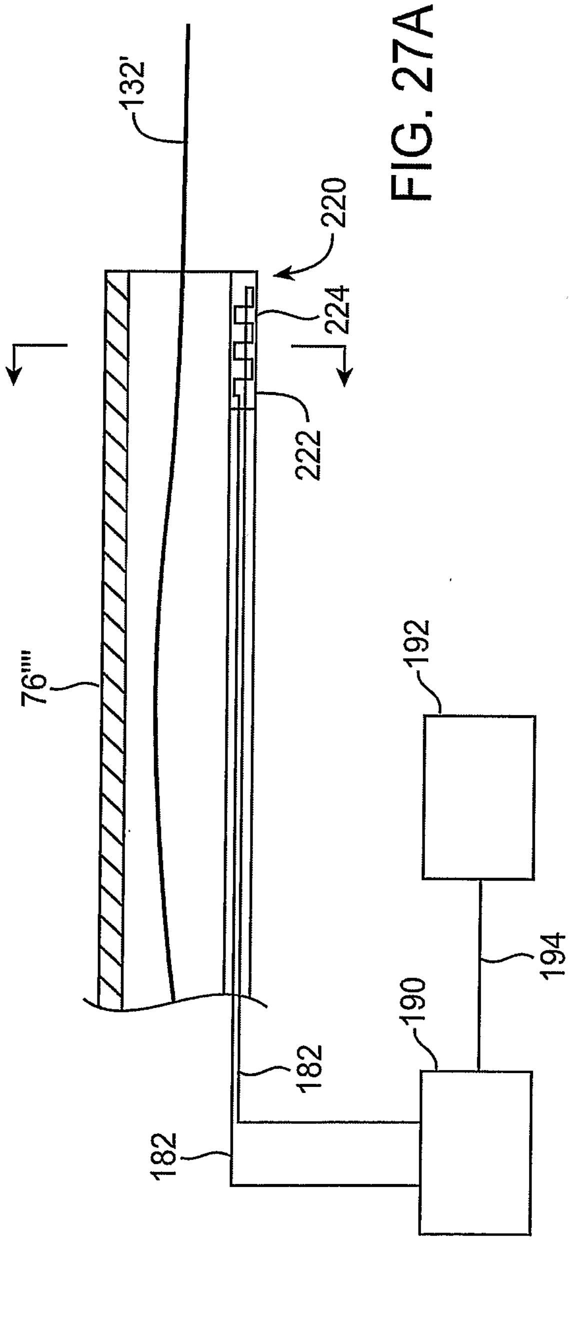

FIG. 27A

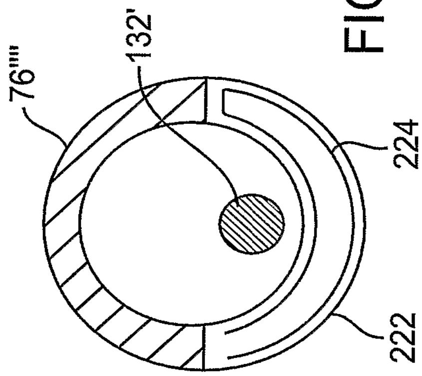

FIG. 27B

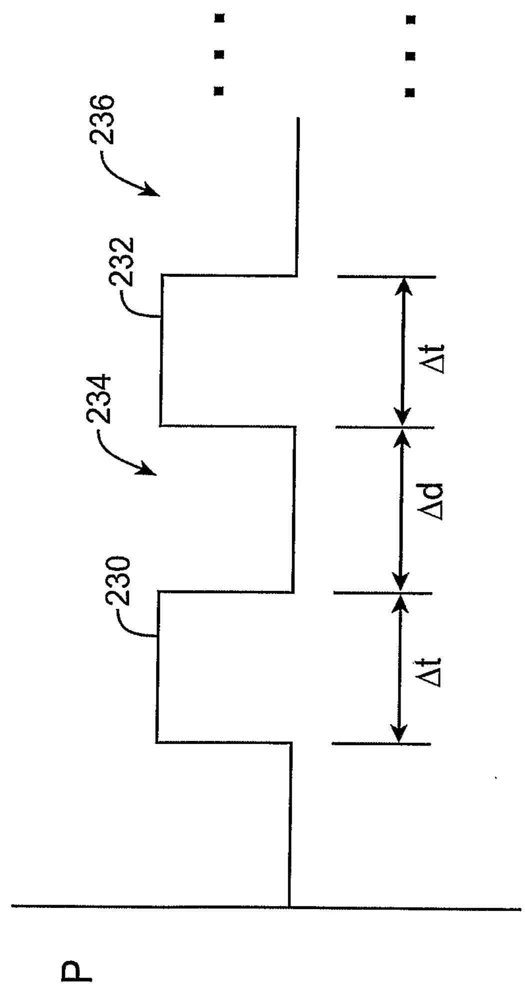

FIG. 28

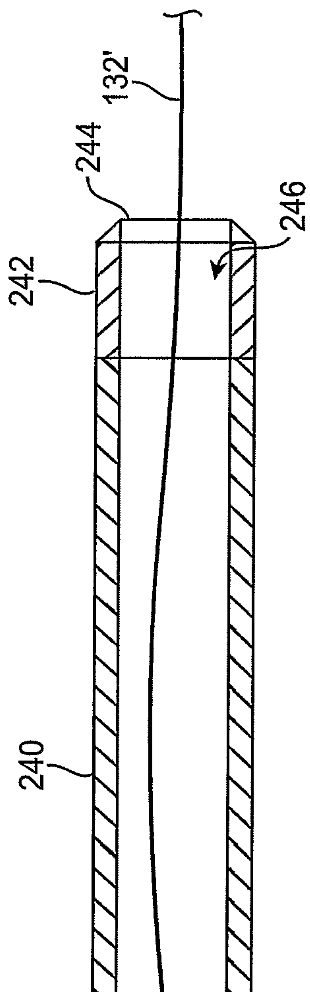

FIG. 29A

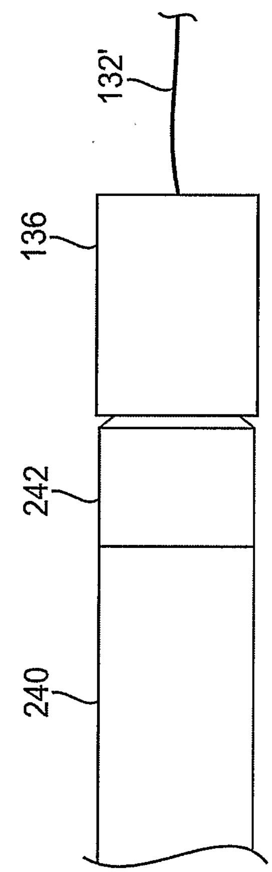

FIG. 29B

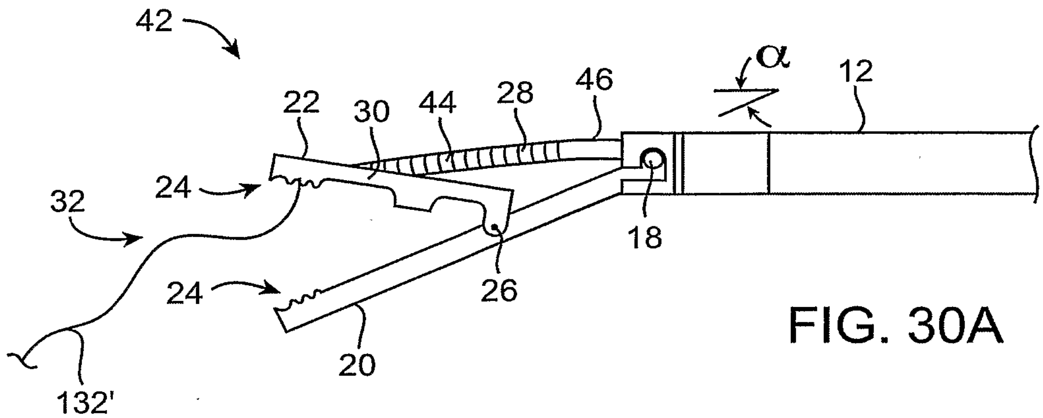

FIG. 30A

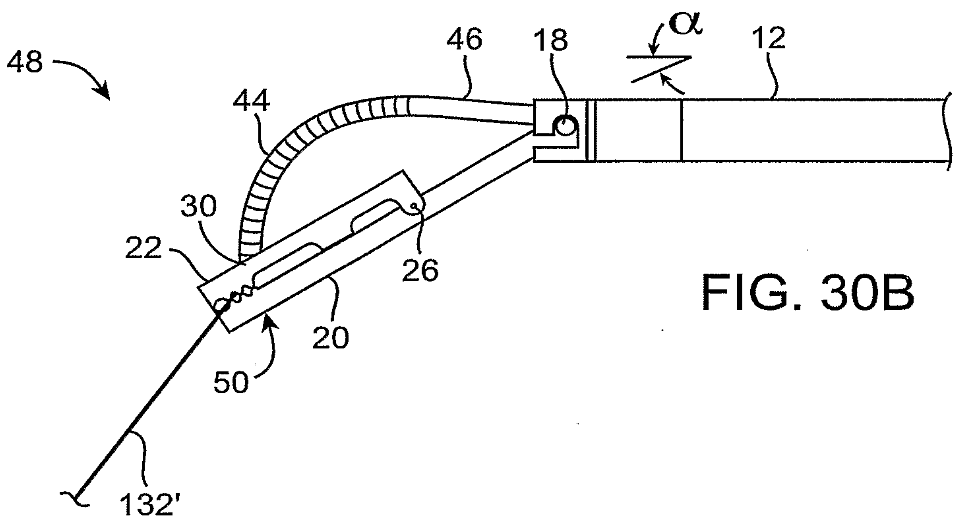

FIG. 30B

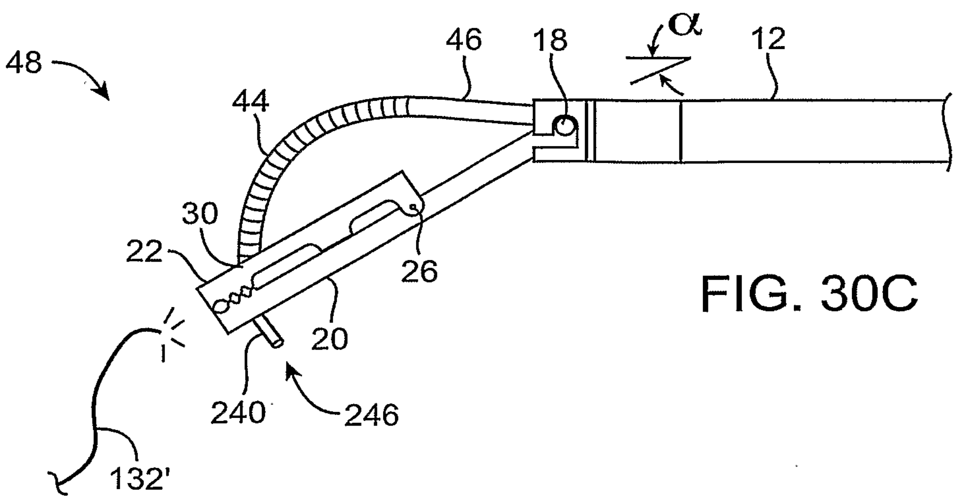

FIG. 30C

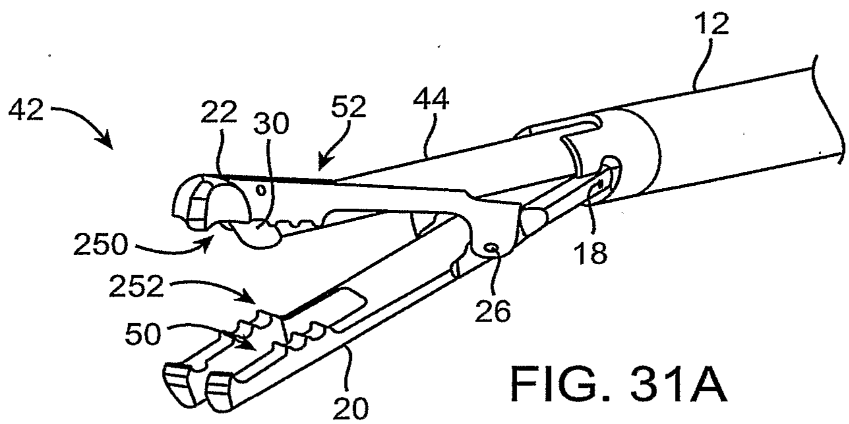

FIG. 31A

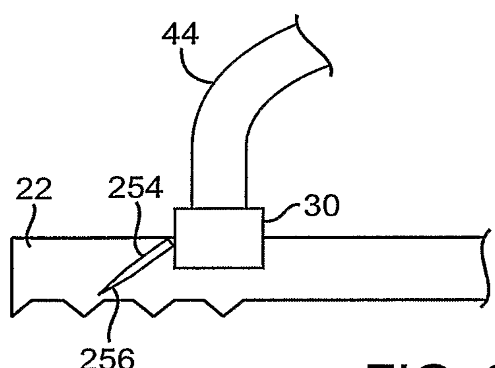

FIG. 31B

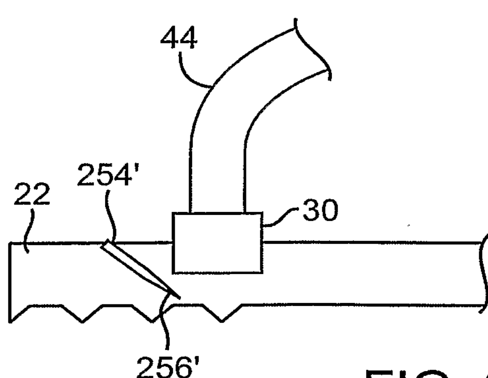

FIG. 31C

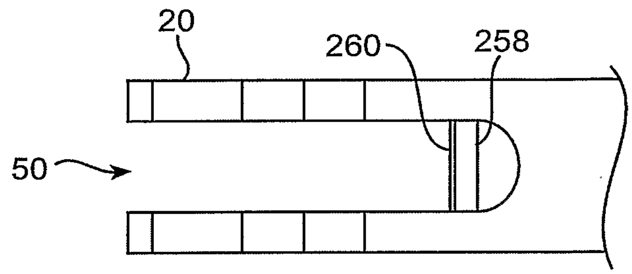

FIG. 31D

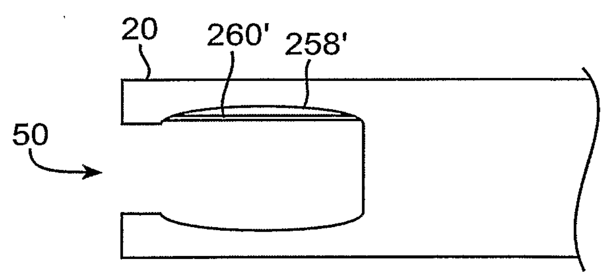

FIG. 31E

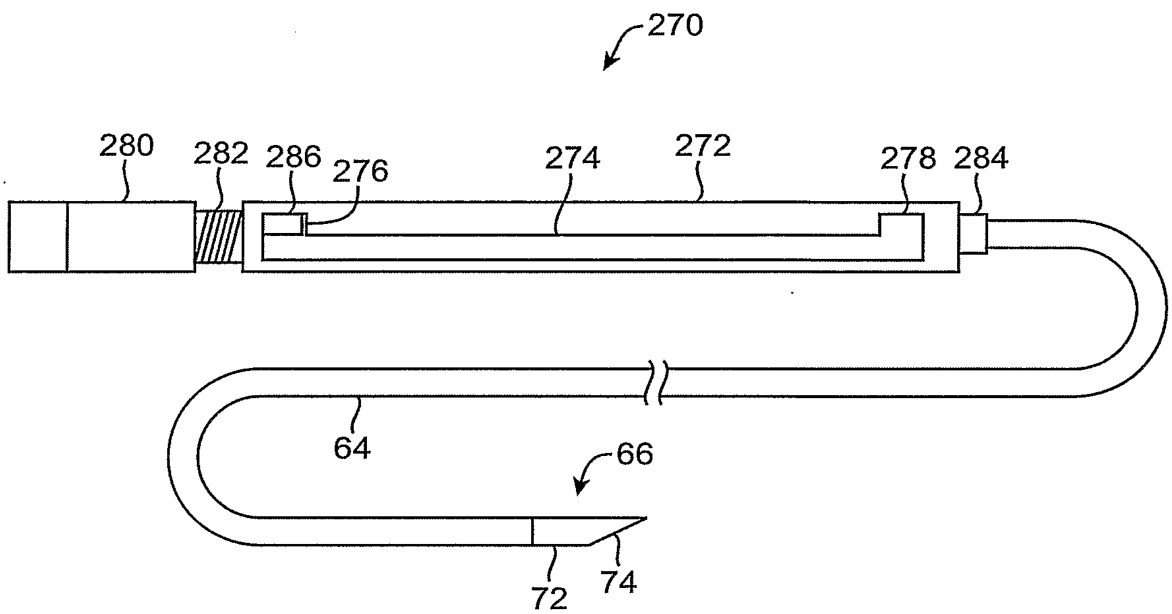

FIG. 32

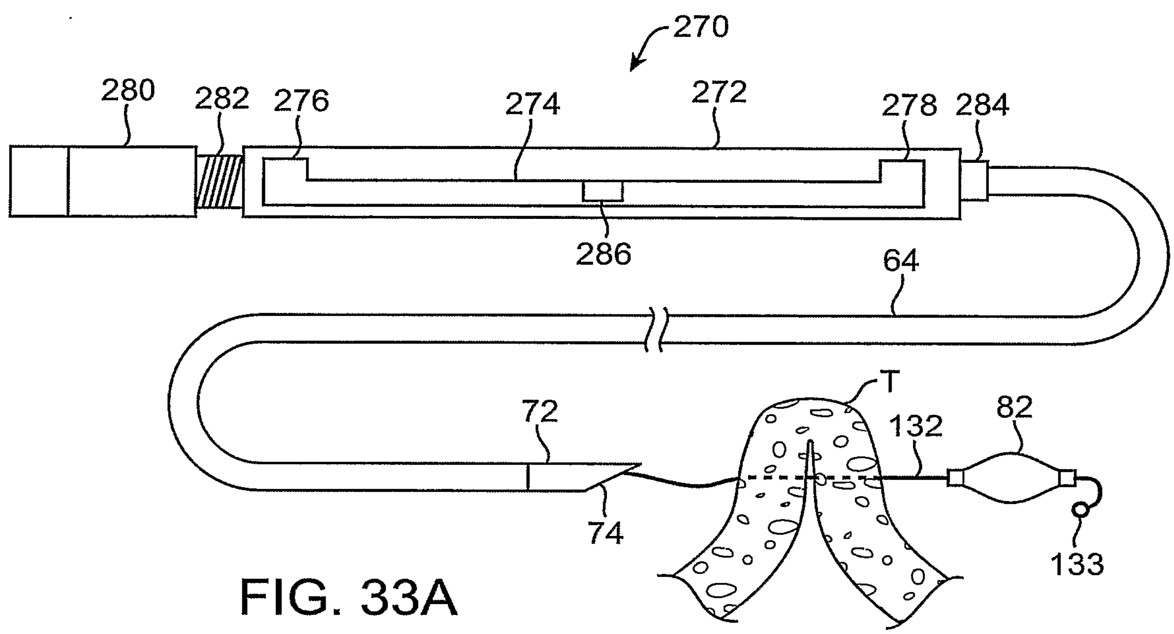

FIG. 33A

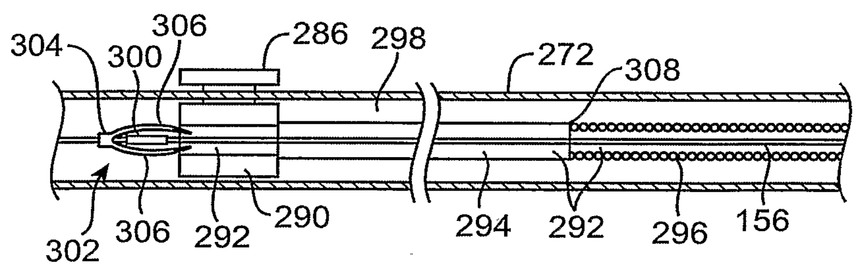

FIG. 33B

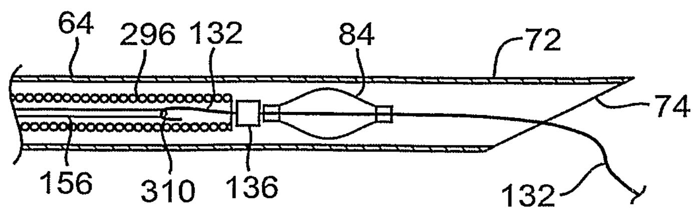

FIG. 33C

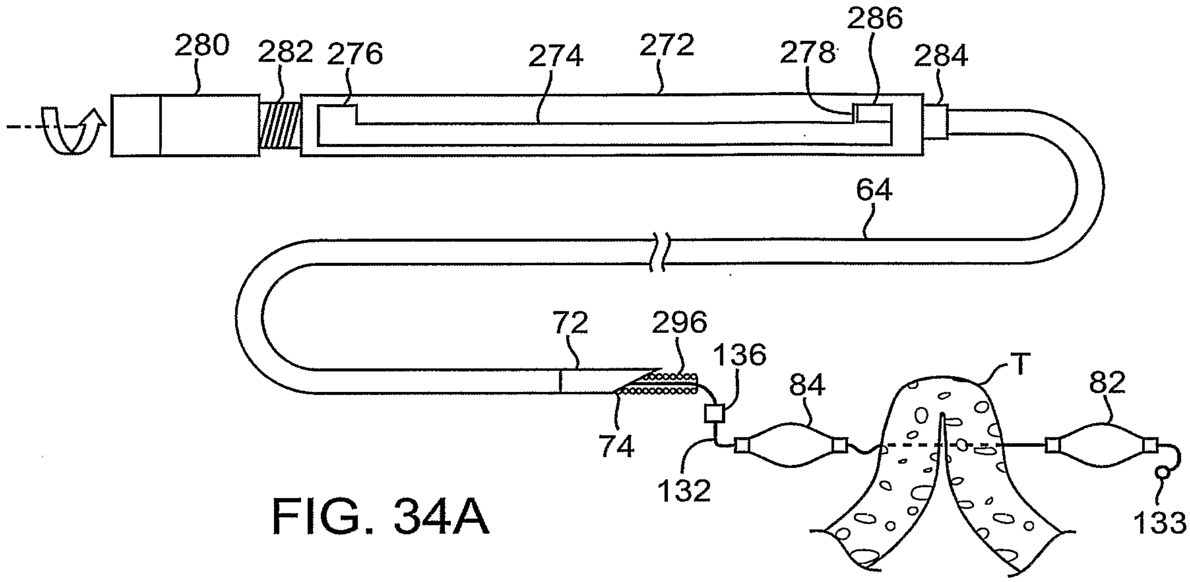

FIG. 34A

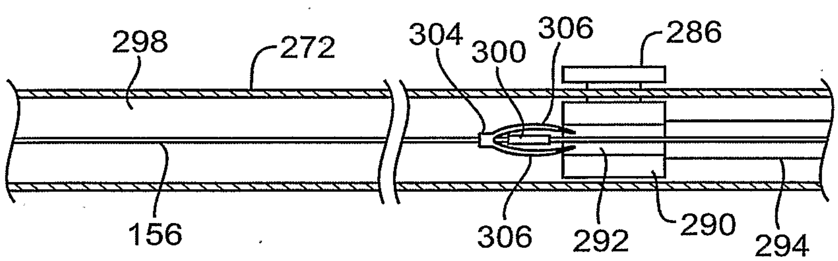

FIG. 34B

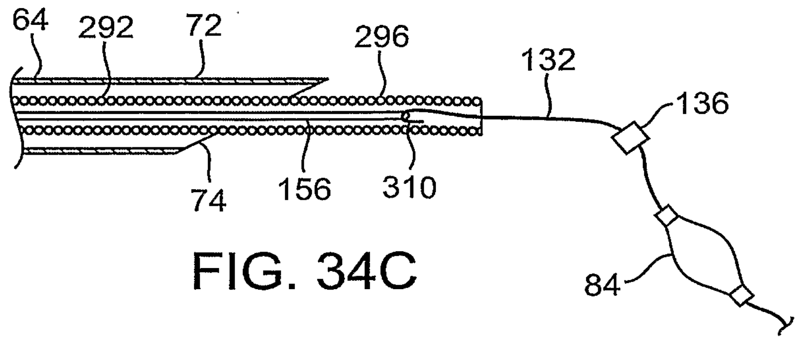

FIG. 34C

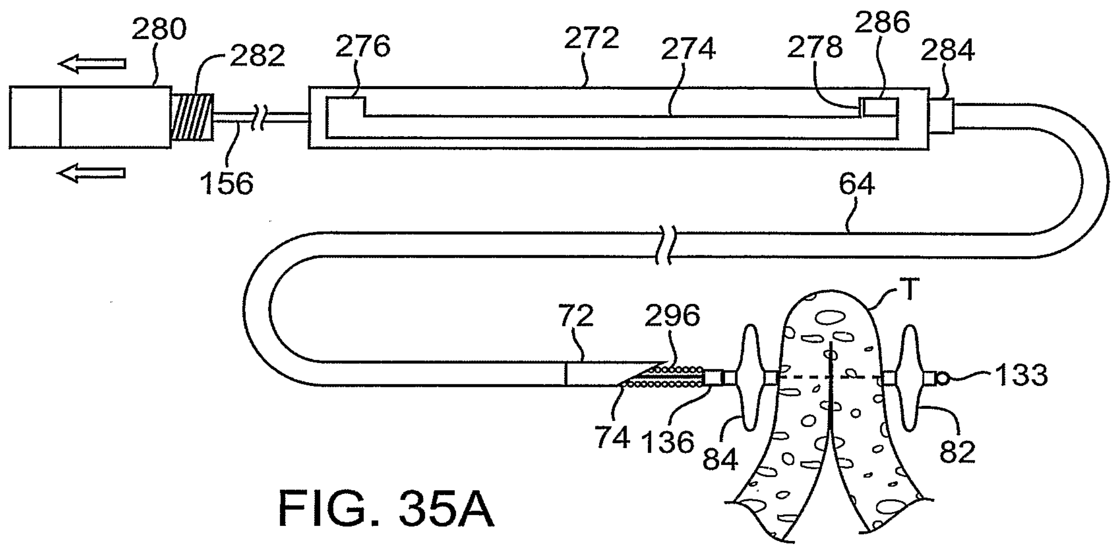

FIG. 35A

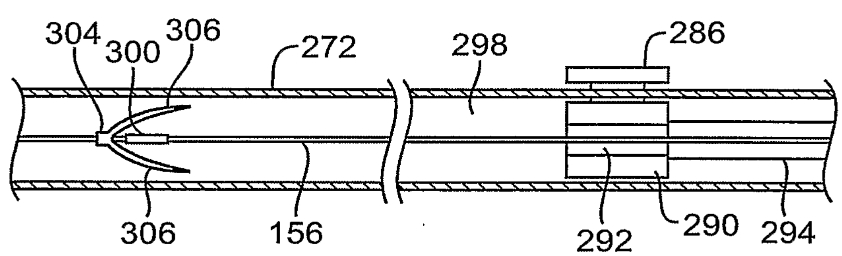

FIG. 35B

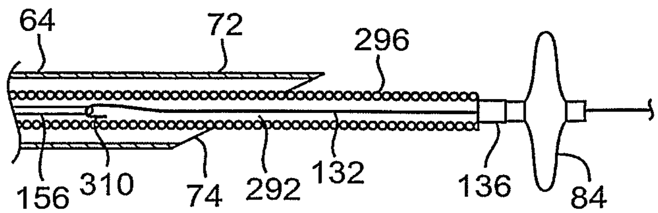

FIG. 35C

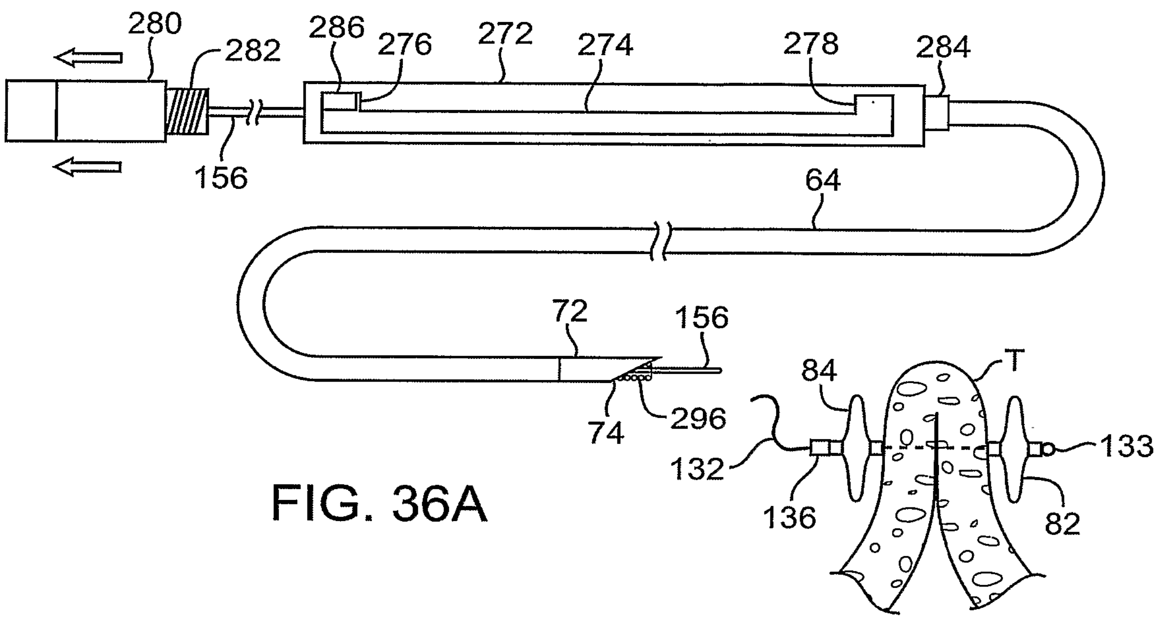

FIG. 36A

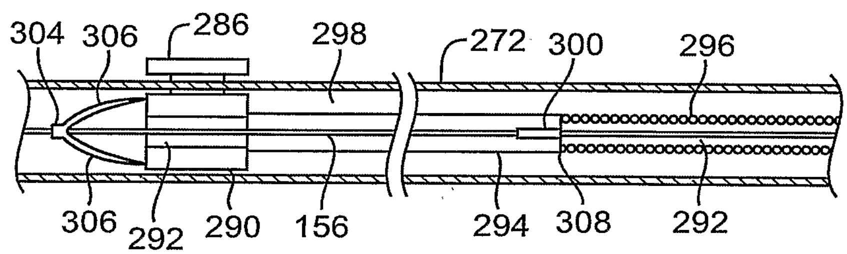

FIG. 36B

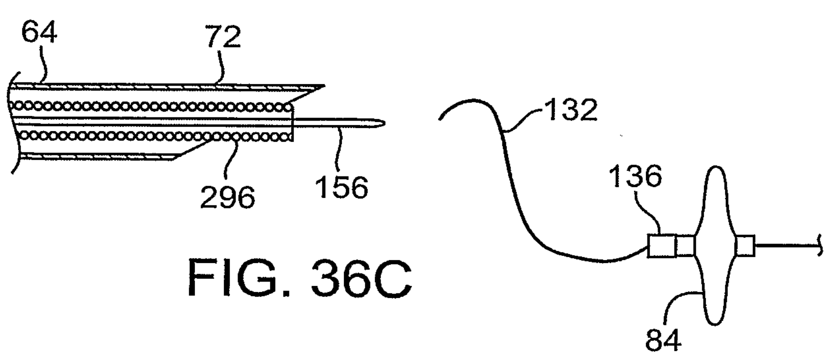

FIG. 36C